NELLCOR

SERVICE MANUAL

NPB-195 Pulse Oximeter

MALLINCKRODT

Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

To contact Mallinckrodt's representative: In the United States, call 1-800-635-5267 or 314-654-2000; outside the United States, call your local Mallinckrodt representative.

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SECTION 1: INTRODUCTION

1.1 Manual Overview
1.2 NPB-195 Pulse Oximeter Description
1.3 Power-On Self Test
1.4 Related Documents

1.1 MANUAL OVERVIEW

This manual contains information for servicing the Nellcor® model NPB-195 pulse oximeter. Only qualified service personnel should service this product. Before servicing the NPB-195, read the operator's manual carefully for a thorough understanding of operation.

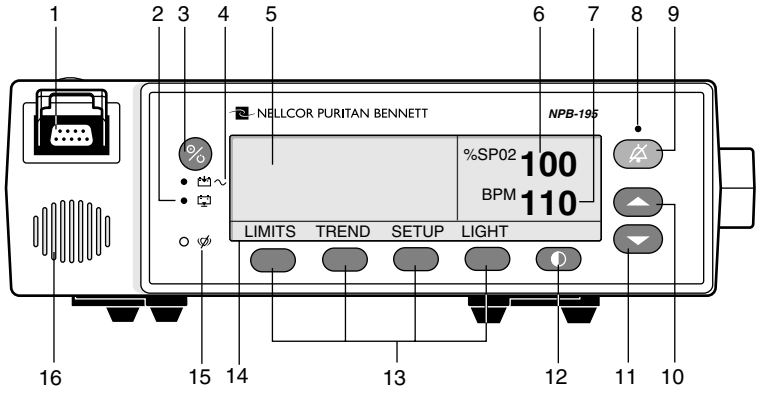
WARNING: Explosion hazard. Do not use the NPB-195 pulse oximeter in the presence of flammable anesthetics.

1.2 NPB-195 PULSE OXIMETER DESCRIPTION

The NPB-195 is a portable pulse oximeter intended for use as a continuous noninvasive monitor of arterial oxygen saturation (SpO_2) and pulse rate. It can be used on adult, pediatric and neonatal patients. Oxygen saturation and pulse rate are displayed digitally along with a plethysmographic waveform or a ten-segment blip bar which indicates pulse intensity.

Through the use of the four softkeys, the operator can access trend information, select an alarm limit to be changed, choose the language to be used, adjust the internal time clock, and change communications protocol. The NPB-195 can operate on AC power or on an internal battery. This monitor is intended for use in hospital, hospital-type facilities, during intra-hospital transport, and in home environments. The controls and indicators for the NPB-195 are illustrated in Figure 1-1 through Figure 1-3.

Figure 1-2 illustrates the various functions available, and how to access them, through the use of the softkeys. A complete explanation of the keys is provided in the NPB-195 operator's manual.



1. SpO2 Sensor Port
2. Low Battery Indicator
3. Power On/Standby Button
4. AC/Battery Charging Indicator
5. Waveform Display
6. %SpO2 Indicator
7. Pulse **B**eats **P**er **M**inute display
8. Alarm Silence Indicator
9. Alarm Silence Button
10. Adjust Up Button
11. Adjust Down Button
12. Contrast Button
13. Softkeys
14. Menu Bar
15. Pulse Search Indicator
16. Speaker

Figure 1-1: NPB-195 Front Panel

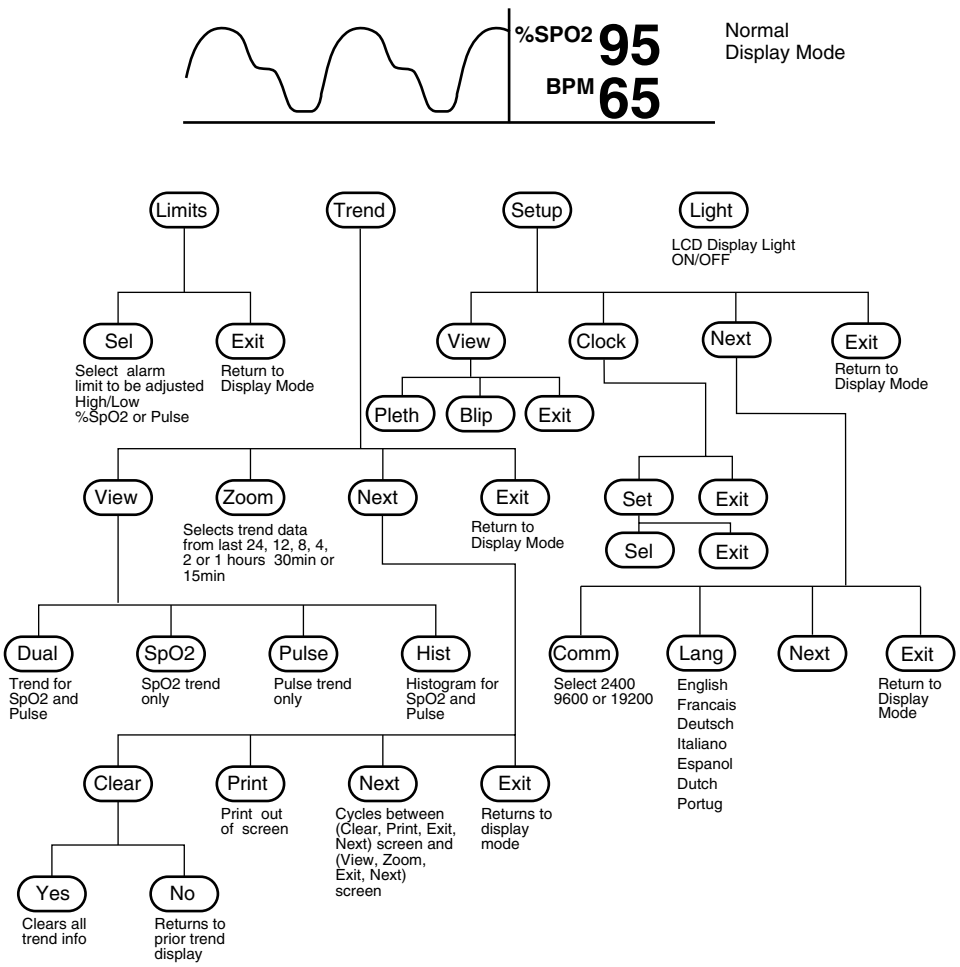
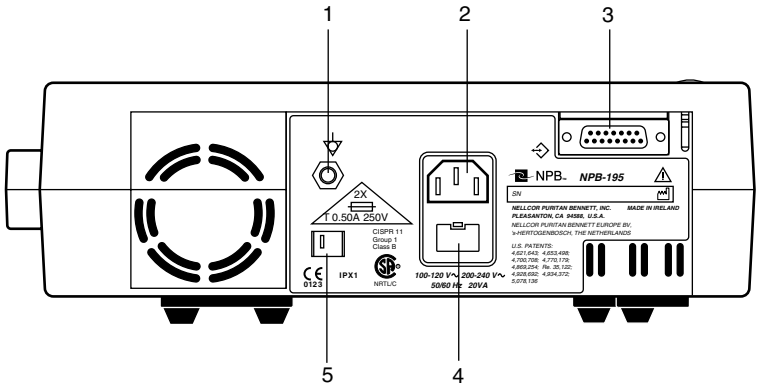


Figure 1-2: User Softkey Map



1. Equipotential (ground) Terminal
2. AC Inlet
3. DB-15 Interface Connector
4. Fuse Receptacle
5. Voltage Selection Switch

Figure 1-3: NPB-195 Rear Panel

1.3 POWER-ON SELF TEST

When the NPB-195 is turned on it will perform a POST (Power-On Self Test). During POST the following sequence should occur:

- All indicator lights illuminate
- All pixels in the LCD display illuminate
- The backlight turns on and the Nellcor Puritan Bennett logo and software version are displayed

Upon successful completion of POST, the NPB-195 sounds a 1-second tone indicating that the monitor has passed the test.

If the start-up sequence is not completed as described above, do not use the monitor.

The software version is often needed when calling Mallinckrodt's Technical Services Department or your local Mallinckrodt representative for technical assistance. Record the software version and have it available prior to requesting technical assistance.

1.4 RELATED DOCUMENTS

To perform test and troubleshooting procedures, and to understand the principles of operation and circuit analysis sections of this manual, you must know how to operate the monitor. Refer to the NPB-195 operator's manual. To understand the various Nellcor sensors that work with the monitor, refer to the individual sensor's directions for use.

SECTION 2: ROUTINE MAINTENANCE

2.1 Cleaning
2.2 Periodic Safety and Functional Checks
2.3 Battery

2.1 CLEANING

Caution: Do not immerse the NPB-195 or its accessories in liquid or clean with caustic or abrasive cleaners. Do not spray or pour any liquid on the monitor or its accessories.

To clean the NPB-195, dampen a cloth with a commercial, nonabrasive cleaner and wipe the exterior surfaces lightly. Do not allow any liquids to come in contact with the power connector, fuse holder, or switches. Do not allow any liquids to penetrate connectors or openings in the instrument cover. Wipe sensor cables with a damp cloth. For sensors, follow each sensor's directions for use.

2.2 PERIODIC SAFETY AND FUNCTIONAL CHECKS

The following checks should be performed at least every 2 years by a qualified service technician.

1. Inspect the exterior of the NPB-195 for damage.
2. Inspect safety labels for legibility. If the labels are not legible, contact Mallinckrodt's Technical Services Department or your Mallinckrodt representative.
3. Verify that the unit performs properly as described in paragraph 3.3.
4. Perform the electrical safety tests detailed in paragraph 3.4. If the unit fails these electrical safety tests, do not attempt to repair the NPB-195. Contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative.
5. Inspect the fuses for proper value and rating (F1 & F2 = 0.5 amp slow blow).

2.3 BATTERY

Mallinckrodt recommends replacing the instrument battery every 2 years. When the NPB-195 is going to be stored for 3 months or more, remove the battery prior to storage. To replace or remove the battery, refer to Section 6, *Disassembly Guide*.

If the NPB-195 has been stored for more than 30 days, charge the battery as described in paragraph 3.3.1. A fully discharged battery requires 14 hours in standby, or 18 hours if in use, to receive a full charge. The battery is being charged anytime the instrument is plugged into AC.

SECTION 3: PERFORMANCE VERIFICATION

3.1 Introduction
3.2 Equipment Needed
3.3 Performance Tests
3.4 Safety Tests

3.1 INTRODUCTION

This section discusses the tests used to verify performance following repairs or during routine maintenance. All tests can be performed without removing the NPB-195 cover. All tests except the battery charge and battery performance tests must be performed as the last operation before the monitor is returned to the user.

If the NPB-195 fails to perform as specified in any test, repairs must be made to correct the problem before the monitor is returned to the user.

3.2 EQUIPMENT NEEDED

Equipment	Description
Digital multimeter (DMM)	Fluke Model 87 or equivalent
Durasensor® oxygen transducer	DS-100A
Oxisensor® *II* oxygen transducer	D-25
Pulse oximeter tester	SRC-2
Safety analyzer	Must meet current AAMI ES1/1993 & IEC 601-1/1998 specifications
Sensor extension cable	EC-4 or EC-8
Serial interface cable	EIA-232 cable (optional)
Stopwatch	Manual or electronic

3.3 PERFORMANCE TESTS

The battery charge procedure should be performed before monitor repairs whenever possible. It should also be performed before returning the instrument to use.

Note: This section is written using Mallinckrodt factory-set defaults. If your institution has preconfigured custom defaults, those values will be displayed. Factory defaults can be restored using the configuration mode procedure described in paragraph 4.2.1 below.

3.3.1 Battery Charge

Perform the following procedure to fully charge the battery.

1. Connect the monitor to an AC power source.
2. Verify that the monitor is off and that the AC Power/Battery Charging indicator is lit.

3. Charge the battery for at least 14 hours in standby.

3.3.2 Power-up Performance

The power-up performance tests (3.3.3.1 through 3.3.3.3) verify the following monitor functions:

- 3.3.2.1 Power-On Self-Test
- 3.3.2.2 Power-On Defaults and Alarm Limit Ranges

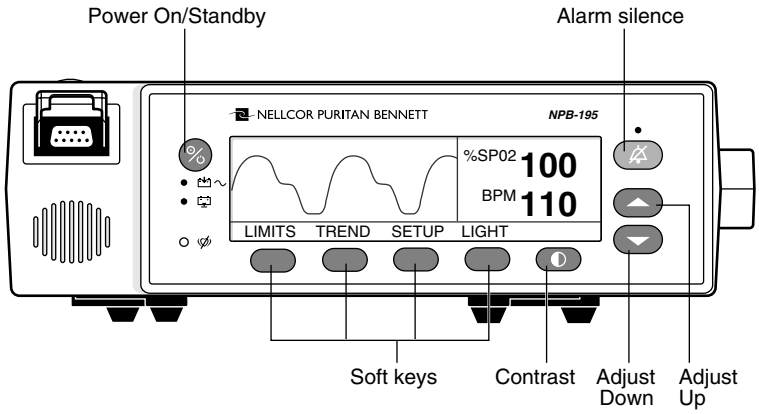


Figure 3-1: NPB-195 Controls

3.3.2.1 Power-On Self-Test

1. Connect the monitor to an AC power source and verify that the AC Power/Battery Charging indicator is lit.
2. Do not connect any input cables to the monitor.

3. Observe the monitor front panel. With the monitor off, press the Power On/Standby button. See Figure 3-1. The monitor must perform the following sequence.

   a. Within 2 seconds all LEDs are illuminated, then all pixels on the LCD display are illuminated, after which, the backlight comes on.

   b. The indicators remain lighted.

   c. The LCD display shows the Nellcor Puritan Bennett logo and the software version of the NPB-195 (Figure 3-2).

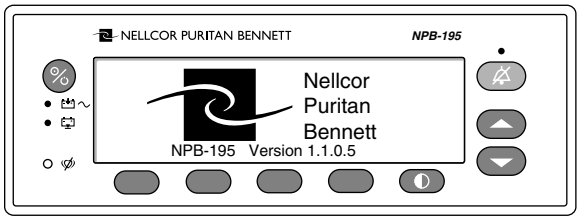


Figure 3-2: Self-Test Display

   d. A 1-second beep sounds indicating proper operation of the speaker, and all indicators turn off except the AC Power/Battery Charging indicators.

   e. The NPB-195 begins normal operation.

3.3.2.2 Power-On Defaults and Alarm Limit Ranges

Note: When observing or changing default limits, a 10-second timeout is in effect. If no action is taken within 10 seconds, the monitor automatically returns to the monitoring display.

Note: The descriptions that follow are based on the assumption that Pleth is the view that has been selected. The steps to changing an alarm limit are the same if the view being used is Blip.

1. Ensure that the monitor is on. Press and release the Limits softkey. Verify that the monitor emits a single beep and the plethysmograph waveform is replaced with a display of the alarm limits. The high alarm limit for %SpO_2 will indicate an alarm limit of "100" inside a box (Figure 3-3).

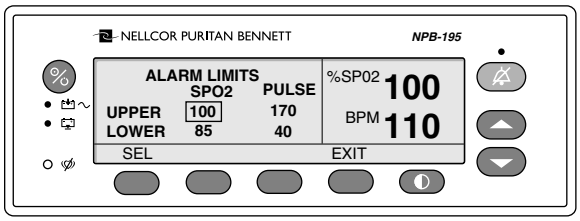


Figure 3-3: Adjusting %SpO_2 Upper Alarm Limit

At the end of 10 seconds, with no activity, normal monitoring is resumed.

2. Press the Limits softkey. Press and hold the Down Arrow button. Verify that the boxed number for %SpO2 upper alarm limit reduces to a minimum of "85."

   Note: A decimal point in the display indicates that the alarm limits have been changed from factory default values.

3. Press the SEL softkey. Verify that the monitor emits a single beep and the box moves to the %SpO**2** lower alarm limit of "85." See Figure 3-4.

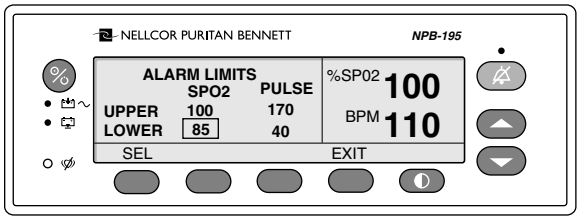


Figure 3-4: Adjusting % SpO2 Lower Alarm Limit

4. Press and hold the Down Arrow button and verify that the %SpO2 lower alarm limit display reduces to a minimum of "20." Press and hold the Up Arrow button and verify that the %SpO2 lower alarm limit display cannot be raised past the upper alarm limit setting of "85." Press the Exit button.

5. Press the Limits softkey and then press the SEL softkey two times. Verify that the monitor emits a beep after each keystroke. The Pulse upper alarm limit should be "170" and should be boxed. See Figure 3-5.

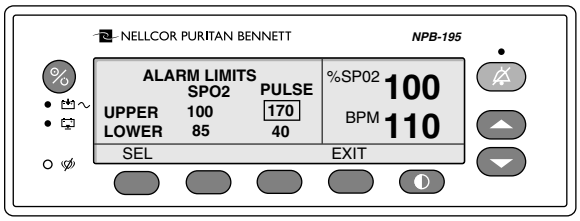


Figure 3-5: Adjusting High Pulse Rate Alarm

6. Press and hold the Down Arrow button. Verify that the Pulse upper alarm limit display reduces to a minimum of "40" and is displayed. Press the Exit button.

7. Press the Limits softkey and then press the SEL softkey three times. Verify that the Pulse lower alarm limit display indicates an alarm limit of "40" and is boxed. See Figure 3-6.

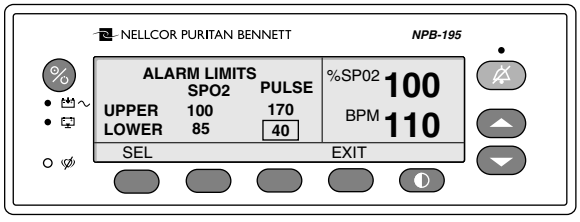


Figure 3-6: Adjusting Low Pulse Rate Alarm

8. Press and hold the Down Arrow button. Verify that the boxed Pulse lower alarm limit display reduces to a minimum of "30."
9. Press and hold the Up Arrow button and verify that the boxed Pulse lower alarm limit display cannot be adjusted above the Pulse high limit of "40."
10. Press the Power On/Standby button to turn the monitor off.
11. Press the Power On/Standby button to turn the NPB-195 back on.
12. Press and release the Limits softkey. Verify that the %SpO_2 upper alarm limit display is boxed and indicates an alarm limit of "100."
13. Press the SEL softkey. Verify that the %SpO_2 lower alarm limit display is boxed and indicates an alarm limit of "85."
14. Press the SEL softkey a second time. Verify that the Pulse upper alarm limit display is boxed and indicates an alarm limit of "170."
15. Press the SEL softkey a third time. Verify that the Pulse lower alarm limit display is boxed and indicates an alarm limit of "40."
16. Press the Power On/Standby button to turn the monitor off.

3.3.3 Hardware and Software Tests

Hardware and software testing include the following tests.

- 3.3.3.1 Operation with a Pulse Oximeter Tester
- 3.3.3.2 General Operation

3.3.3.1 Operation with a Pulse Oximeter Tester

Operation with an SRC-2 pulse oximeter tester includes the following tests.

- 3.3.3.1.1 Alarms and Alarm Silence
- 3.3.3.1.2 Alarm Volume Control
- 3.3.3.1.3 Pulse Tone Volume Control
- 3.3.3.1.4 Dynamic Operating Range

3.3.3.1.1 Alarms and Alarm Silence

1. Connect the SRC-2 pulse oximeter tester to the sensor input cable and connect the cable to the monitor. Set the SRC-2 as follows:

SWITCH	POSITION
RATE	38
LIGHT	LOW
MODULATION	OFF
RCAL/MODE	RCAL 63/LOCAL

2. Press the Power On/Standby button to turn the monitor on. After the normal power-up sequence, press the following softkeys; Setup, View, and Pleth. Verify that the %SpO_2 and Pulse initially indicate zeroes.

3. Move the modulation switch on the SRC-2 to LOW.
4. Verify the following monitor reactions:
   a. The plethysmograph waveform begins to track the artificial pulse signal from the SRC-2.
   b. The pulse tone is heard.
   c. Zeroes are displayed in the %SpO_2 and Pulse displays.
   d. After about 10 to 20 seconds, the monitor displays a saturation and pulse rate as specified by the tester. Verify that the values are within the following tolerances:

      Oxygen Saturation Range 79% to 83%

      Pulse Rate Range 37 to 39 bpm

   e. The audible alarm sounds and both the %SpO_2 and Pulse displays will flash, indicating both parameters have violated the default alarm limits.
5. Press and hold the Alarm Silence button on the front of the monitor for less than 2 seconds. Verify that the %SpO_2 display indicates "60" and the Pulse display indicates "SEC" while the Alarm Silence button is pressed. When the button is released the alarm is silenced.
6. With the alarm silenced verify the following:
   a. The alarm remains silenced.
   b. The Audible Silence indicator lights.
   c. The %SpO_2 and Pulse displays continue to flash.
   d. The pulse tone is still audible.
   e. The audible alarm returns in approximately 60 seconds.
7. Press and hold the Alarm Silence button. Press the Down Arrow button until the Pulse display indicates "30." Press the Up Arrow button and verify that the displays indicate 60 SEC, 90 SEC, 120 SEC, and OFF. Release the button when the display indicates "OFF. "
8. Press and release the Alarm Silence button. Verify that the Alarm Silence Indicator flashes.
9. Wait approximately 3 minutes. Verify that the alarm does not return. After 3 minutes, the alarm silence reminder beeps three times, and will continue to do so at approximately 3-minute intervals.

3.3.3.1.2 Alarm Volume Control

After completing the procedure in paragraph 3.3.3.1.1 above:

1. Press and hold the Alarm Silence button and verify the following:
   a. "OFF" is displayed for approximately 2 seconds.
   b. After 2 seconds, a steady tone is heard at the default alarm volume setting, the %SpO_2 display indicates "VOL," and the Pulse display indicates the default setting of 5.
2. While still pressing the Alarm Silence button, press the Down Arrow button until an alarm volume setting of 1 is displayed. Verify that the volume of the alarm has decreased but is still audible.
3. Continue pressing the Alarm Silence button and press the Up Arrow button to increase the alarm volume setting to a maximum value of 10. Verify that the volume increases. Press the Down Arrow button until a comfortable audio level is attained.
4. Release the Alarm Silence button. The tone will stop.

3.3.3.1.3 Pulse Tone Volume Control

1. Press the Up Arrow button and verify that the beeping pulse tone sound level increases.
2. Press the Down Arrow button and verify that the beeping pulse tone decreases until it is no longer audible. Press the Up Arrow button to return the beep volume to a comfortable level.

3.3.3.1.4 Dynamic Operating Range

The following test sequence verifies proper monitor operation over a range of input signals.

1. Connect the SRC-2 to the NPB-195 and turn the NPB-195 on.
2. Place the SRC-2 in the RCAL 63/LOCAL mode.
3. Set the SRC-2 as indicated in Table 3-1. Verify that the NPB-195 readings are within the indicated tolerances. Allow the monitor several seconds to stabilize the readings.

Note: A asterisk "*" indicates values that produce an alarm. Press the Alarm Silence button to silence the alarm.

Table 3-1: Dynamic Operating Range

SRC-2 Settings			**NPB-195 Indications**	
RATE	LIGHT	MODULATION	SpO_2	Pulse Rate
38	HIGH2	LOW	79 - 83*	35 - 41*
112	HIGH1	HIGH	79 - 83*	109 - 115
201	LOW	LOW	79 - 83*	198 - 204*
201	LOW	HIGH	79 - 83*	198 - 204*

3.3.3.1.5 Nurse Call

Note: The Nurse Call tests must be performed with the instrument operating on AC power.

1. Connect the negative lead of a voltmeter to pin 10 and positive lead to pin 11 of the serial port on the back of the instrument (Figure 10-1). Ensure that the audible alarm is not silenced or turned off.
2. Set the SRC-2 to create an alarm condition. Verify an output voltage at pins 10 and 11 between +5 to +12 VDC.
3. Press the Alarm Silence button. With no active audible alarm, the output voltage at pins 10 and 11 must be between -5 to -12 VDC.
4. Turn the instrument off.

3.3.3.1.6 Operation on Battery Power

1. Turn the instrument on using AC Power.
2. Disconnect the instrument from AC and verify that the AC Power Indicator turns off.
3. Verify that the instrument continues monitoring normally and that the Low Battery Indicator is not lit.

Note: If the Low Battery Indicator is illuminated, perform the procedure outlined in step 3.3.1.

4. Connect the instrument to AC and verify that the AC Power Indicator turns on and that the instrument is monitoring normally.

3.3.3.2 General Operation

The following tests are an overall performance check of the system:

- 3.3.3.2.1 LED Excitation Test
- 3.3.3.2.2 Operation with a Live Subject

3.3.3.2.1 LED Excitation Test

This procedure uses normal system components to test circuit operation. A Nellcor *Oxisensor® II* oxygen transducer, model D-25, is used to examine LED intensity control. The red LED is used to verify intensity modulation caused by the LED intensity control circuit.

1. Connect the monitor to an AC power source.
2. Connect an EC-4 or EC-8 sensor input cable to the monitor.
3. Connect a D-25 sensor to the sensor input cable.
4. Press the Power On/Standby button to turn the monitor on.
5. Leave the sensor open with the LEDs and photodetector visible.
6. After the monitor completes its normal power-up sequence, verify that the sensor LED is brightly lit.

7. Slowly move the sensor LED in proximity to the photodetector element of the sensor. Verify, as the LED approaches the optical sensor, that the LED intensity decreases.
8. Open the sensor and notice that the LED intensity increases.
9. Repeat step 7 and the intensity will again decrease. This variation is an indication that the microprocessor is in proper control of LED intensity.
10. Turn the NPB-195 off.

3.3.3.2.2 Operation with a Live Subject

Patient monitoring involves connecting the monitor to a live subject for a qualitative test.

1. Ensure that the monitor is connected to an AC power source.
2. Connect an EC-4 or EC-8 sensor extension cable to the monitor.
3. Connect a Nellcor *Durasensor*® oxygen transducer, model DS-100A, to the sensor input cable.
4. Clip the DS-100A to the subject as recommended in the sensor's directions for use.
5. Press the Power On/Standby button to turn the monitor on and verify that the monitor is operating.
6. The monitor should stabilize on the subject's physiological signal in about 15 to 30 seconds. Verify that the oxygen saturation and pulse rate are reasonable for the subject.

3.4 SAFETY TESTS

NPB-195 safety tests meet the standards of, and are performed in accordance with, IEC 601-1 (EN 60601-1, Second Edition, 1988; Amendment 1, 1991-11, Amendment 2, 1995-03) and UL 2601-1 (August 18, 1994), for instruments classified as Class 1 and TYPE BF and AAMI Standard ES1 (ANSI/AAMI ES1 1993).

- Ground Integrity
- Electrical Leakage

3.4.1 Ground Integrity

This test checks the integrity of the power cord ground wire from the AC plug to the instrument chassis ground. The current used for this test is $\leq$ 6V RMS 50 or 60 Hz and 25 A.

1. Connect the monitor AC mains plug to the analyzer as recommended by the analyzer operating instructions.
2. Connect the analyzer resistance input lead to the equipotential terminal (grounding lug) on the rear panel of the instrument. Verify that the analyzer indicates 100 milliohms or less.

3.4.2 Electrical Leakage

The following tests verify the electrical leakage of the monitor:

- Earth Leakage Current
- Enclosure Leakage Current
- Patient Applied Risk Current
- Patient Isolation Risk Current (Mains on Applied Part)

Note: For the following tests, ensure that the AC switch on the rear of the instrument is configured for the AC voltage being supplied.

3.4.2.1 Earth Leakage Current

This test is in compliance with IEC 601-1 (earth leakage current) and AAMI Standard ES1 (earth risk current). The applied voltage for AAMI ES1 is 120 VAC 60 Hz, for IEC 601-1 the voltage is 264 VAC 50 to 60 Hz. All measurements shall be made with the power switch in both the "On" and "Off" positions. See Table 3-2.

1. Connect the monitor AC plug to the electrical safety analyzer as recommended by the analyzer operating instructions.
2. The equipotential terminal is not connected to ground.

Table 3-2: Earth Leakage Current Limits

AC POLARITY	LINE CORD	NEUTRAL CORD	LEAKAGE CURRENT
Normal	Closed	Closed	500 µA
Reversed	Closed	Closed	500 µA
Normal	Open	Closed	1000 µA
Normal	Closed	Open	1000 µA

3.4.2.2 Enclosure Leakage Current

This test is in compliance with IEC 601-1 (enclosure leakage current) and AAMI Standard ES1 (enclosure risk current). This test is for ungrounded enclosure current, measured between enclosure parts and earth. The applied voltage for AAMI/ANSI is 120 VAC 60 Hz, and for IEC 601-1 the applied voltage is 264 VAC 50 to 60 Hz.

1. Connect the monitor AC plug to the electrical safety analyzer as recommended by the analyzer operating instructions.
2. Place a 200-cm^2 foil in contact with the instrument case, making sure the foil is not in contact with any metal parts of the enclosure that may be grounded. Measure the leakage current between the foil and earth.

The analyzer leakage indication must not exceed values listed in Table 3-3:

Table 3-3: Enclosure Leakage Current Limits

AC LINE CORD	NEUTRAL LINE CORD	POWER LINE GROUND CABLE	IEC 601-1	AAMI/ANSI ES1 STANDARD
Closed	Closed	Closed	100 µA	100 µA
Closed	Closed	Open	500 µA	300 µA
Closed	Open	Closed	500 µA	300 µA
Open	Closed	Closed	500 µA	100 µA
Open	Open	Closed	500 µA	300 µA
Open	Closed	Open	500 µA	300 µA

3.4.2.3 Patient Applied Risk Current

This test is in compliance with AAMI Standard ES1 (patient applied risk current), and IEC 601-1 (patient auxiliary current). The leakage current is measured between any individual patient connection and power (earth) ground. The applied voltage for AAMI/ANSI is 120 VAC 60 Hz, and for IEC 601-1 the applied voltage is 264 VAC 50 to 60 Hz.

1. Configure the electrical safety analyzer as follows:

   Function: Patient Leakage

   Range: µA

2. Connect the monitor AC plug to the electrical safety analyzer as recommended by the analyzer operating instructions for Patient Leakage Current.
3. Connect the patient leakage input lead of the electrical safety analyzer to all pins of the monitor's patient cable at the end of the cable.
4. The equipotential terminal is not connected to ground.
5. All functional earth terminals are not connected to ground.
6. Measure the leakage current between the patient connector and earth. See Table 3-4.

Table 3-4: Patient Leakage Current Limits

AC LINE POLARITY	NEUTRAL LINE	POWER LINE GROUND CABLE	IEC 601-1	AAMI/ANSI ES1 STANDARD
Normal	Closed	Closed	100 µA	10 µA
Normal	Open	Closed	500 µA	50 µA
Normal	Closed	Open	500 µA	50 µA
Reverse	Closed	Closed	100 µA	10 µA
Reverse	Open	Closed	500 µA	50 µA
Reverse	Closed	Open	500 µA	50 µA

3.4.2.4 Patient Isolation Risk Current - (Mains Voltage on the Applied Part)

This test is in compliance with AAMI Standard ES1 (patient isolation risk current [sink current]), and IEC 601-1 (patient leakage current). Patient Leakage Current is the measured value in a patient connection if mains voltage is connected to that patient connection. The applied voltage for AAMI/ANSI is 120 VAC 60 Hz, and for IEC 601-1 the applied voltage is 264 VAC 50 to 60 Hz.

Warning: AC mains voltage will be present on the patient applied part terminals during this test. Exercise caution to avoid electrical shock hazard.

1. Configure the electrical safety analyzer as follows:

   Function: Patient Leakage (Mains On Applied Part)

   Range: µA

2. Connect the monitor AC plug to the electrical safety analyzer as recommended by the operating instructions for patient sink (leakage) current.
3. Connect the patient leakage input lead to the electrical safety analyzer to all connectors in the patient cable at the patient end of the cable.
4. The equipotential terminal is not connected to ground.
5. All functional earth terminals are not connected to ground.
6. The analyzer leakage current must not exceed the values shown in Table 3-5.

Table 3-5: Patient Leakage Current Test Configurations - Mains Voltage on the Applied Part

AC LINE POLARITY	NEUTRAL LINE	POWER LINE GROUND CABLE	IEC 601-1	AAMI/ANSI ES1 STANDARD
Normal	Closed	Closed	5 mA	50 µA
Reverse	Closed	Closed	5 mA	50 µA

SECTION 4: POWER-ON SETTINGS AND SERVICE FUNCTIONS

4.1 Introduction
4.2 Power-on Settings
4.3 Service Functions

4.1 INTRODUCTION

This section discusses how to reconfigure power-on default values, access the service functions, and set the clock.

4.2 POWER-ON SETTINGS

The following paragraphs describe how to change power-on default settings.

Through the use of softkeys shown in Figure 1-2, the user can change alarm limits, the type of display, baud rate, time and date, and trends to view. A decimal point is added to the right of a display when the alarm limit for that display has been changed to a value that is not a power-on default value. If the new value is saved as a power-on default value, the decimal point will be removed. By using the service functions, changes can be saved as power-on default values.

Some values cannot be saved as power-on default values. An SpO_2 Low limit less than 80 will not be saved as a power-on default. Audible Alarm Off will not be accepted as a power-on default. An attempt to save either of these values as a default will result in an invalid tone. Both values can be selected for the current patient, but they will be lost when the instrument is turned off.

4.2.1 Factory Default Settings

Factory default settings for the NPB-195 are listed in Table 4-1. Refer to the Operator's manual for changing the parameters listed in Table 4-1. Set desired parameter limits as desired. Refer to paragraph 4-3 to apply these new parameters as default parameters.

Table 4-1: Factory Default Settings

Parameter	Default Value
SpO_2 High	100%
SpO_2 Low	85%
Pulse Rate High	170 bpm
Pulse Rate Low	40 bpm
Alarm Volume	Level 5
Alarm Silence Duration	60 seconds
Alarm Silence Restriction	Sound Reminder
Pulse Beep Volume	Level 4
Baud Rate	9600
Display	Pleth
Trend	Saturation
Contrast	Mid-range
Language	English

4.3 SERVICE FUNCTIONS

4.3.1 Introduction

Service functions can be used to select institutional defaults, and to access information about the patient or instrument. Only a Mallinckrodt Customer Service Engineer should access some of the items available through the service functions. These functions will be described in the text to follow.

4.3.2 Accessing the Service Functions

All service functions are accessible only if the sensor cable is disconnected from the instrument. Simultaneously press the 4th softkey from the left and the contrast button for more than 3 seconds. The menu bar will change to the headings listed in Figure 4-1.

Note: If a "Sensor Disconnected" prompt appears on the screen, press the Alarm Silence button and repeat the above procedure.

Note: If the above steps are performed with a sensor cable connected, only the Param and Exit softkeys appear on the screen.

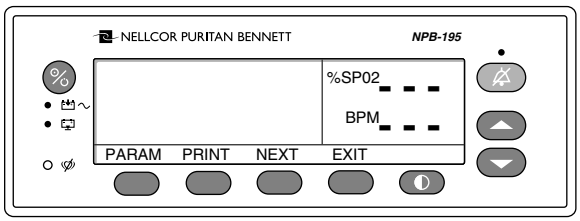


Figure 4-1: Service Function Softkeys

Figure 4-2 can be used as a quick reference showing how to reach different softkey functions. Items reached through the Param softkey can be accessed during normal operation. Functions provided by the Print and Next softkeys cannot be accessed when a sensor cable is connected to the instrument. Each of the various functions is described in the text to follow.

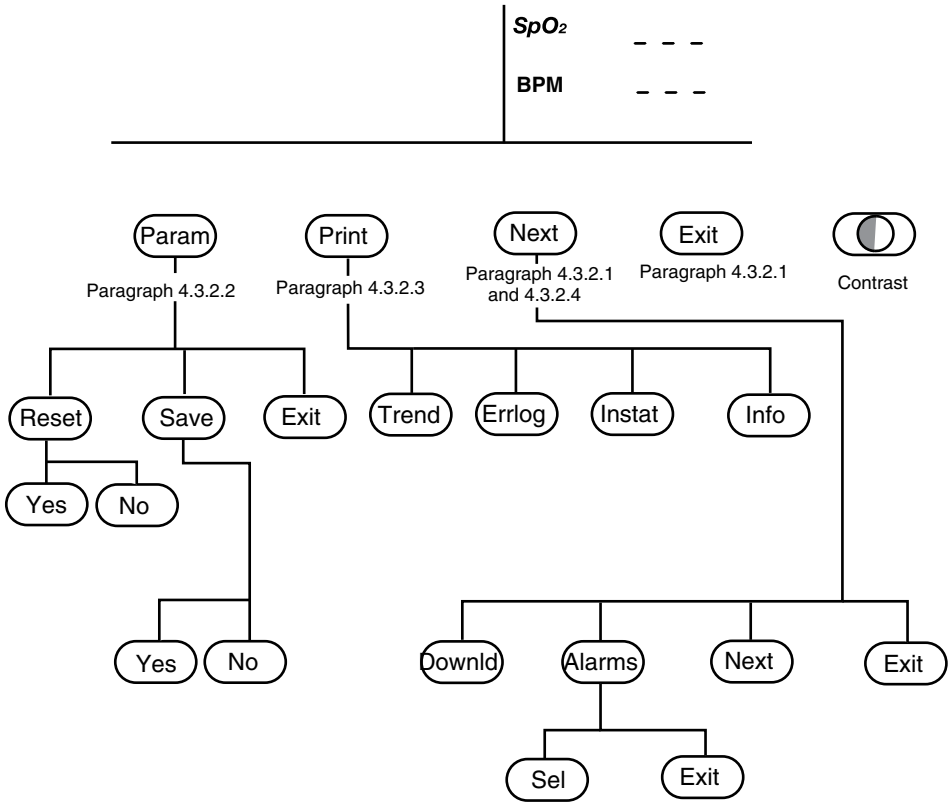


Figure 4-2: Service Function Softkey Map

4.3.2.1 Exit & Next Softkeys

NEXT

There are not enough buttons to display all of the options that are available at some levels of the menu. Pressing the Next button allows you to view additional options available at a given menu level.

EXIT

To back up one menu level, press the Exit button. The service functions can be exited by repeatedly pressing the Exit button.

4.3.2.2 Param

When the Param softkey is pressed, the function of the softkeys changes as shown in Figure 4-3. These options can be accessed without disconnecting the sensor cable from the instrument.

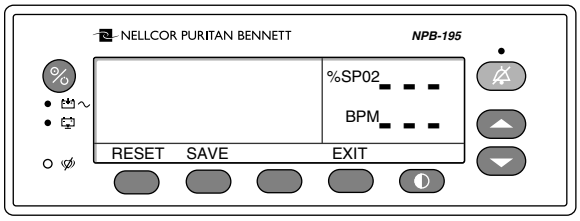


Figure 4-3: Param Softkeys

RESET

The Reset button can be used if alarm values stored in memory have been changed from factory default values. If Yes is pressed, the instrument sounds three tones and the alarm limits return to factory default values. When No is pressed, no changes are made to the values stored in memory.

SAVE

When adjustable values are changed from factory default, the Save button can be used to preserve the settings as institutional power-on default values. Pressing Yes stores the current settings in memory. The instrument sounds three tones indicating that the change has been saved as power-on default values. If an invalid tone is sounded, the parameter cannot be saved as a power-on default (see paragraph 4.2).

These values will continue to be used through power-on and -off cycles until they are changed and saved again, or until they are reset. If No is pressed, the changed values will not be saved.

4.3.2.3 Print

PRINT

Accessing the Print softkey makes three printouts available. See Section 10 for information about how to make connections to the serial port and how data is presented in a printout. The appropriate printout can be selected by pressing the corresponding softkey. Figure 4-4 represents the softkey configuration after the Print softkey has been selected.

Up to 24 hours of data can be retrieved from the printouts described below. When the instrument is turned on, a line of data is recorded every 5 seconds. As an example, an instrument that is used 6 hours a week would take 4 weeks to fill its memory.

Note: The two-letter codes and the symbols that occur in the printout are described in Table 10-2.

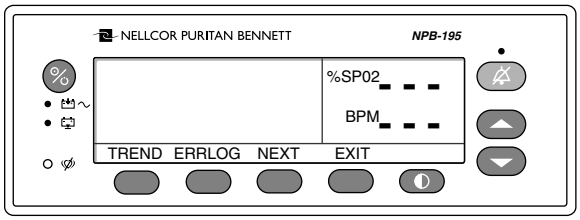


Figure 4-4: Print Softkeys

TREND

A Trend printout will include all data recorded for up to 24 hours of monitoring since the last Clear data was performed. A trend line is recorded every 5 seconds or whenever an alarm condition has occurred. Figure 4-5 is an example of a Trend printout.

NPB-195 Version 1.0.0.000		TREND	SpO2 Limit: 30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	PR (bpm)	PA	
01-Jul-97 14:00:00	100	120	220	
01-Jul-97 14:00:05	100	124	220	
01-Jul-97 14:00:10	100	190	220	
01-Jul-97 14:00:15	100	190	220	
01-Jul-97 18:00:43	- - -	- - -	- - -	
01-Jul-97 18:00:48	- - -	- - -	- - -	
NPB-195 Version 1.0.0.000		Trend	SpO2 Limit: 80-100%	PR Limit: 60-180 bpm
Time	%SpO2	PR (bpm)	PA	
01-Jul-97 18:00:53	- - -	- - -	- - -	
01-Jul-97 18:00:58	- - -	- - -	- - -	
01-Jul-97 18:01:03	98	100	140	
01-Jul-97 18:01:08	98	181*	190	
01-Jul-97 18:01:13	99	122	232	
Output Complete				

Figure 4-5: Trend Printout

The first two lines are the column heading lines. The first line includes information about the type of instrument delivering the information, the software level, type of printout, and alarm parameters. The second line consists of the column headings These lines are printed out every 25 lines or when a change to an alarm parameter is made. Patient data is represented with a date and time stamp for the data. In the example above, the "- - -" means that a sensor was connected but no data was being received (patient disconnect). Patient data that is outside of an alarm limit is marked with an asterisk (*).

At the end of the printout "Output Complete" will be printed. This indicates that there was no corruption of data. If the Output Complete statement is not printed at the end of the printout, the data must be considered invalid.

ERRLOG

A list of all the errors recorded in memory can be obtained by pressing the Errlog softkey. The first line the type of instrument producing the printout, software level, type of printout and the time of the printout. The second line lists the column headings. An example of an Errlog printout is shown in Figure 4-6.

NPB-195 Version 1.0.0.000		Error Log	Time:	14600:00:07
Op Time	Error	Task	Addr	Count
10713:21:03	52	12	48F9	100
00634:26:01	37	4	31A2	3
Output Complete				

Figure 4-6: Errlog Printout

INSTAT

A Delete softkey, described in the Operator's manual, allows the user to clear the most recent trend data. Cleared trends can still be retrieved from the instrument through an Instat printout. Instat can be accessed by pressing Next after the Print softkey has been selected.

The oldest cleared trend will become Trend 01 on the Instat printout. If a Trend 01 already existed in memory from an earlier Clear, the next clear will become Trend 02. Every time a Clear is performed from the User Softkeys, the number of existing trends will increase by 1.

Figure 4-7 illustrates an Instat printout. The first line is for instrument type, software revision level, type of printout, and alarm parameter settings. The second line lists the column headings. A line of data is recorded for every 5 seconds of instrument operation. Up to 24 hours of instrument operation data can be recorded.

The final line on the printout is Output Complete. This indicates that data has been successfully transmitted with no corruption. If no Output Complete line is printed, the data should be considered invalid.

NPB-195	Version 1.0.0.000	Instrument	SpO2 Limit:	30-100%	PR Limit: 100-180 bpm
TIME	Trend 01	%SpO2	PR (bpm)	PA	SpO2 Status	UIF Status	Aud
01-Jul-97	14:00:00	- - -	- - -	- - -	SD	BU LB AO	L
01-Jul-97	14:00:05	- - -	- - -	- - -	PS	BU LB AO	
01-Jul-97	14:00:10	100	120	220		BU LB	
01-Jul-97	14:00:15	100	120	220		BU LB	
NPB-195	Version 1.0.0.000	Instrument	SpO2 Limit:	80-100%	PR Limit: 60-180 bpm
TIME	Trend 01	%SpO2	PR (bpm)	PA	SpO2 Status	UIF Status	Aud
01-Jul-97	14:24:24	79*	58*	220	PS SL PL	BU LB	M
01-Jul-97	14:24:29	79*	57*	220	PS SL PL	BU LB AS	M
01-Jul-97	14:24:29	0*	0*	- - -	PS LP SL PL	BU LB AS	H
NPB-195	Version 1.0.0.000	Instrument	SpO2 Limit:	80-100%	PR Limit: 60-180 bpm
TIME	Trend 01	%SpO2	PR (bpm)	PA	SpO2 Status	UIF Status	Aud
11-Jul-97	7:13:02	99	132*	220	PH	BU	M
11-Jul-97	7:13:07	99	132*	220	PH	BU	M
11-Jul-97	7:13:12	99	132*	220	PH	BU	M
11-Jul-97	7:13:17	99	132*	220	PH	BU	M
11-Jul-97	7:13:22	99	132*	220	PH	BU	M
11-Jul-97	7:13:27	99	132*	220	PH	BU	M
11-Jul-97	7:13:32	99	132*	220	PH	BU	M
Output Complete							

Figure 4-7: Instat Printout

4.3.2.4 Next

Additional options can be accessed from the main Service Functions menu by pressing the Next softkey. When Next is pressed, the softkeys change to the functions shown in Figure 4-8.

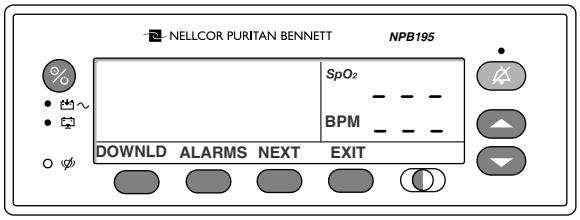


Figure 4-8: Next Softkeys

DOWNLD

When Downld is selected, the instrument will display the revision of the Boot Code. To exit Downld, cycle power to the instrument by pressing the Power On/Standby button.

ALARMS

Pressing the Alarms softkey can change characteristics of the audible alarm. When the Alarms softkey is pressed, the softkey's functions change as shown in Figure 4-9.

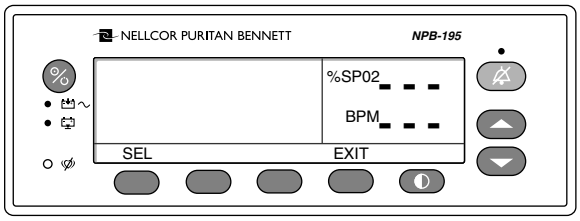


Figure 4-9: Alarms Softkeys

SEL

The Sel softkey is used to select what function of the audible alarm is going to be changed. A box can be cycled between two choices: Allow and Reminder.

When Allow is selected, a choice is given between allowing an audible alarm off or disabling the audible alarm off. Pressing the Up or Down arrow key cycles between yes and no. If Yes is selected, the operator has the option of selecting Audible Alarm Off. If No is selected, the operator will not be given the option of selecting Audible Alarm Off.

If the audible alarm is disabled or silenced, a reminder tone can be sounded every three minutes to notify the user of this condition. The Up and Down arrow keys can be used to change the choice from Yes to No. Selecting Yes enables the Reminder and No disables the Reminder.

SECTION 5: TROUBLESHOOTING

5.1 Introduction
5.2 How to Use this Section
5.3 Who Should Perform Repairs
5.4 Replacement Level Supported
5.5 Obtaining Replacement Parts
5.6 Troubleshooting Guide
5.7 Error Codes

5.1 INTRODUCTION

This section explains how to troubleshoot the NPB-195 if problems arise. Tables are supplied that list possible monitor difficulties, along with probable causes, and recommended actions to correct the difficulty.

5.2 HOW TO USE THIS SECTION

Use this section in conjunction with Section 3, *Performance Verification*, and Section 7, *Spare Parts*. To remove and replace a part you suspect is defective, follow the instructions in Section 6, *Disassembly Guide*. The circuit analysis section in the Technical Supplement offers information on how the monitor functions.

5.3 WHO SHOULD PERFORM REPAIRS

Only qualified service personnel should open the monitor housing, remove and replace components, or make adjustments. If your medical facility does not have qualified service personnel, contact Mallinckrodt's Technical Services or your local Mallinckrodt representative.

5.4 REPLACEMENT LEVEL SUPPORTED

The replacement level supported for this product is to the printed circuit board (PCB) and major subassembly level. Once you isolate a suspected PCB, follow the procedures in Section 6, *Disassembly Guide,* to replace the PCB with a known good PCB. Check to see if the trouble symptom disappears and that the monitor passes all performance tests. If the trouble symptom persists, swap back the replacement PCB with the suspected malfunctioning PCB (the original PCB that was installed when you started troubleshooting) and continue troubleshooting as directed in this section.

5.5 OBTAINING REPLACEMENT PARTS

Mallinckrodt's Technical Services provides technical assistance information and replacement parts. To obtain replacement parts, contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative. Refer to parts by the part names and part numbers listed in Section 7, *Spare Parts*.

5.6 TROUBLESHOOTING GUIDE

Problems with the NPB-195 are separated into the categories indicated in Table 5-1. Refer to the paragraph indicated for further troubleshooting instructions.

Note: Taking the recommended actions discussed in this section will correct the majority of problems you may encounter. However, problems not covered here can be resolved by calling Mallinckrodt's Technical Services Department or your local Mallinckrodt representative.

Table 5-1: Problem Categories

Problem Area	Refer to Paragraph
1. Power • No power-up on AC and/or DC • Fails power-on self-test • Powers down without apparent cause	5.6.1
2. Buttons • Monitor does not respond properly to buttons	5.6.2
3. Display/Alarms • Displays do not respond properly • Alarms or other tones do not sound properly or are generated without apparent cause	5.6.3
4. Operational Performance • Displays appear to be operational, but monitor shows no readings • Suspect readings	5.6.4
5. Serial Port • NPB-195 serial port not functioning properly	5.6.5

5.6.1 Power

Power problems are related to AC and/or DC. Table 5-2 lists recommended actions to resolve power problems.

Table 5-2: Power Problems

Condition	Recommended Action
1. Battery Low indicator lights steadily while NPB-195 is connected to AC and battery is fully charged.	1. Ensure that the NPB-195 is plugged into an operational AC outlet and the AC indicator is on. 2. Check the fuses. The fuses are located in the Power Entry Module as indicated in paragraph 6.3 and Figure 6-1 of the Disassembly Guide. Replace if necessary. 3. Open the monitor as described in section 6. Verify the power supply's output to the battery while on AC. Disconnect the battery leads from the battery and connect a DVM to them. The voltage measured should be 6.80 VDC ± 0.15 VDC, and the current should be 400 mA ± 80 mA. Replace power supply if above values are not met. 4. Check the ribbon connection from the bottom enclosure to the UIF PCB, as instructed in paragraph 6.11 of the *Disassembly Guide* section. If the connection is good, replace the UIF PCB.
2. The NPB-195 does not operate when disconnected from AC power.	1. The battery may be discharged. To recharge the battery, refer to paragraph 3.3.1, Battery Charge. The monitor may be used with a less than fully charged battery but with a corresponding decrease in operating time from that charge. 2. If the battery fails to hold a charge, replace the battery as indicated in Section 6, *Disassembly Guide*.
3. Battery Low indicator on during DC operation and an alarm is sounding.	There are 15 minutes or less of usable charge left on the NPB-195 battery before the instrument shuts off. At this point, if possible, cease use of the NPB-195 on battery power, connect it to an AC source and allow it to recharge (approximately 14 hours). The NPB-195 may continue to be used while it is recharging. (A full recharge of the battery while the monitor is being used takes 18 hours.)
4. Battery does not charge.	1. Replace battery if more than 2 years old. 2. Open the monitor as described in Section 6. Verify the power supply's output to the battery while on AC. Disconnect the battery leads from the power supply and connect a DVM to them. The voltage measured should be 6.8 VDC ± 0.15 and the current should be 400 mA ± 80 mA. Replace power supply if above values are not met.

5.6.2 Buttons

Table 5-3 lists symptoms of problems relating to non-responsive buttons and recommended actions. If the action requires replacement of a PCB, refer to Section 6, *Disassembly Guide*.

Table 5-3: Button Problems

Condition	Recommended Action
1. The NPB-195 responds to some, but not all buttons.	1. Replace Top Housing assembly. 2. If the buttons still do not work, replace the UIF PCB.
2. The NPB-195 turns on but does not respond to any of the buttons.	1. Replace Top Housing assembly. 2. If the buttons still do not work, replace the UIF PCB.

5.6.3 Display/Alarms

Table 5-4 lists symptoms of problems relating to non-functioning displays, audible tones or alarms, and recommended actions. If the action requires replacement of a PCB or module, refer to Section 6, *Disassembly Guide*.

Table 5-4: Display/Alarms Problems

Condition	Recommended Action
1. Display values are missing or erratic.	1. If the sensor is connected, replace the sensor connector assembly. 2. If the condition persists, replace the sensor extension cable. 3. If the condition still persists, replace the UIF PCB.
2. Display pixels do not light.	1. Check the connection between the UIF PCB and the Display PCB. 2. If the condition does not change, replace the Display PCB. 3. If the condition still persists, replace the UIF PCB.
3. Alarm sounds for no apparent reason.	1. Moisture or spilled liquids can cause an alarm to sound. Allow the monitor to dry thoroughly before using. 2. If the condition persists, replace the UIF PCB.
4. Alarm does not sound.	1. Replace the speaker as described in Section 6, *Disassembly Guide*. 2. If the condition persists, replace the UIF PCB.

5.6.4 Operational Performance

Table 5-5 lists symptoms of problems relating to operational performance (no error codes displayed) and recommended actions. If the action requires replacement of a PCB or module, refer to Section 6, *Disassembly Guide*.

Table 5-5: Operational Performance Problems

Condition	Recommended Action
1. The Pulse AMPLITUDE indicator seems to indicate a pulse, but the digital displays show zeroes.	1. The sensor may be damaged; replace it. 2. If the condition still persists, replace the UIF PCB.
2. SpO_2 or Pulse values change rapidly; Pulse AMPLITUDE indicator is erratic.	1. The sensor may be damp or may have been reused too many times. Replace it. 2. An electrosurgical unit (ESU) may be interfering with performance: – Move the NPB-195 and its cables and sensors as far from the ESU as possible. – Plug the NPB-195 power supply and the ESU into different AC circuits. – Move the ESU ground pad as close to the surgical site as possible and as far away from the sensor as possible. 3. Verify the performance with the procedures detailed in Section 3. 4. If the condition still persists, replace the UIF PCB.

5.6.5 Serial Port

Table 5-6 lists symptoms of problems relating to the serial port and recommended actions. If the action requires replacement of the PCB, refer to Section 6, *Disassembly Guide*.

Table 5-6: Serial Port Problems

Condition	Recommended Action
1. No printout is being received	1. The unit is running on battery power. Connect to an AC source. 2. The monitor's baud rate does not match the printer. Change the baud rate of the monitor following instructions in paragraph 10.2. 3. If the condition still persists, replace the UIF PCB.
2. The nurse call is not working.	1. The unit is running on battery power. Connect to an AC source. 2. Verify connections are made between pins 10 (GND) and 11 (nurse call) of the serial port. 3. Verify output voltage between ground pin 10 and pin 11 is -3 to -10 VDC (no alarm) and +3 to +10 VDC (during alarm) 4. If the condition still persists, replace the UIF PCB.

5.7 ERROR CODES

An error code is displayed when the NPB-195 detects a non-correctable failure. When this occurs, the unit will stop monitoring, sound a low priority alarm that cannot be silenced, clear patient data from the display, and display an error code. Table 5-7 provides a complete list of error codes and possible solutions.

Table 5-7: Error Codes

Code	Meaning	Possible Solutions
1	POST failure	Replace UIF PCB
4	Battery dead	1. Check the voltage selector switch. 2. Charge battery for 14 hours 3. Leads of battery reversed (see paragraph 6.6) 4. Replace battery
5	Too many microprocessor resets within a period of time	1. Cycle power 2. Replace UIF PCB if code 5 repeatedly occurs 3. Replace Power Supply
6	Boot CRC error	Replace UIF PCB
7	Error on UIF PCB	1. Cycle power to clear error. 2. Check voltage selector switch for proper setting. 3. Replace UIF PCB
11	Flash ROM corruption	Replace UIF PCB
76	Error accessing EEPROM	Replace UIF PCB
80	Institutional default values lost and reset to factory default values	1. Cycle power 2. Replace UIF PCB if code 80 repeatedly occurs
82	Time clock lost	1. Reset time clock 2. Battery power was lost; check the battery 3. Replace the Power Supply
84	Internal communications error	Replace UIF PCB

SECTION 6: DISASSEMBLY GUIDE

6.1 Introduction
6.2 Prior to Disassembly
6.3 Fuse Replacement
6.4 Monitor Disassembly
6.5 Monitor Reassembly
6.6 Battery Replacement
6.7 Power Entry Module Removal/Installation
6.8 Power Supply Removal/Installation
6.9 Cooling Fan Removal/Installation
6.10 Display PCB Removal/Installation
6.11 UIF PCB Removal/Installation
6.12 Alarm Speaker Removal/Installation

6.1 INTRODUCTION

The NPB-195 can be disassembled down to all major component parts, including:

- PCBs
- battery
- cables
- chassis enclosures

The following tools are required:

- small, Phillips-head screwdriver
- medium, Phillips-head screwdriver
- small blade screwdriver
- needle-nose pliers or 1/4-inch socket
- torque wrench, 10 inch-pounds (1.13 newton-meters)

WARNING: Before attempting to open or disassemble the NPB-195, disconnect the power cord from the NPB-195.

Caution: Observe ESD (electrostatic discharge) precautions when working within the unit.

Note: Some spare parts have a business reply card attached. When you receive these spare parts, please fill out and return the card.

6.2 PRIOR TO DISASSEMBLY

1. Turn the NPB-195 Off by pressing the Power On/Standby button.
2. Disconnect the monitor from the AC power source.

6.3 FUSE REPLACEMENT

1. Complete procedure in paragraph 6.2.
2. Disconnect the power cord from the back of the monitor.
3. Remove the fuse drawer from the power module by pressing down on the tab in the center and pulling out as shown in Figure 6-1.

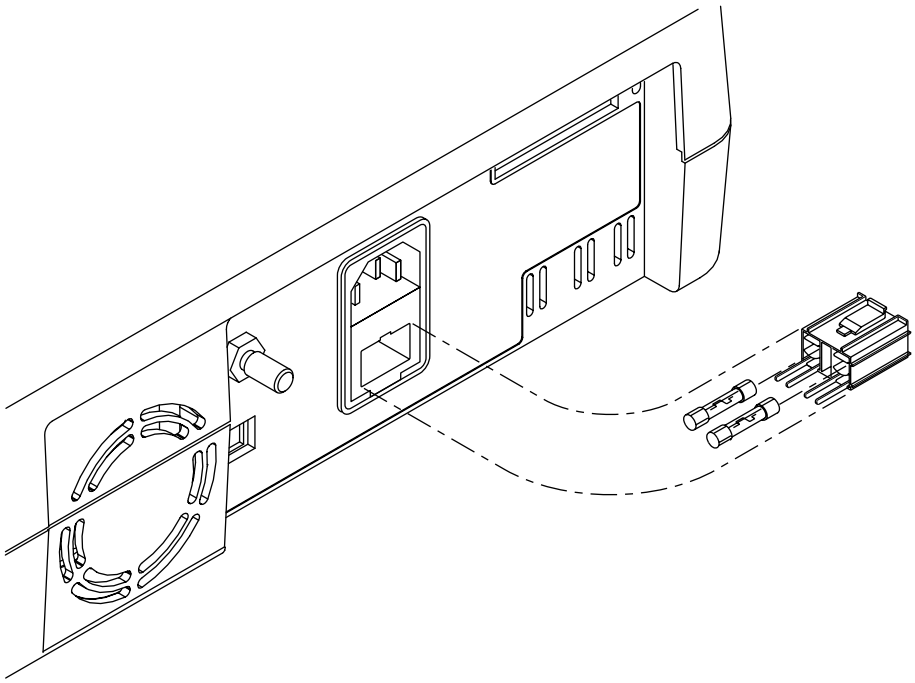


Figure 6-1: Fuse Removal

4. Put new fuses of equivalent size and rating in the drawer and reinsert the drawer in the power module.

6.4 MONITOR DISASSEMBLY

1. Set the NPB-195 upside down, as shown in Figure 6-2.

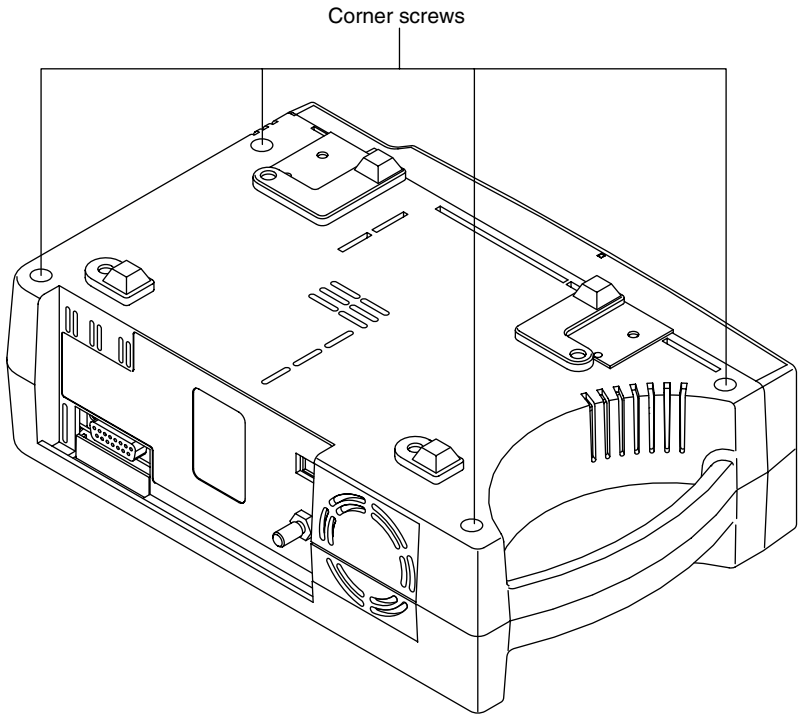


Figure 6-2: NPB-195 Corner Screws

2. Remove the four corner screws.

Caution: Observe ESD (electrostatic discharge) precautions when disassembling and reassembling the NPB-195 and when handling any of the components of the NPB-195.

3. Separate the top case from the bottom case of the monitor, being careful not to stress the wire harnesses between the cases. Place the two halves of the monitor on the table as shown in Figure 6-3.

4. Disconnect the Power Supply from J6 on the UIF PCB.

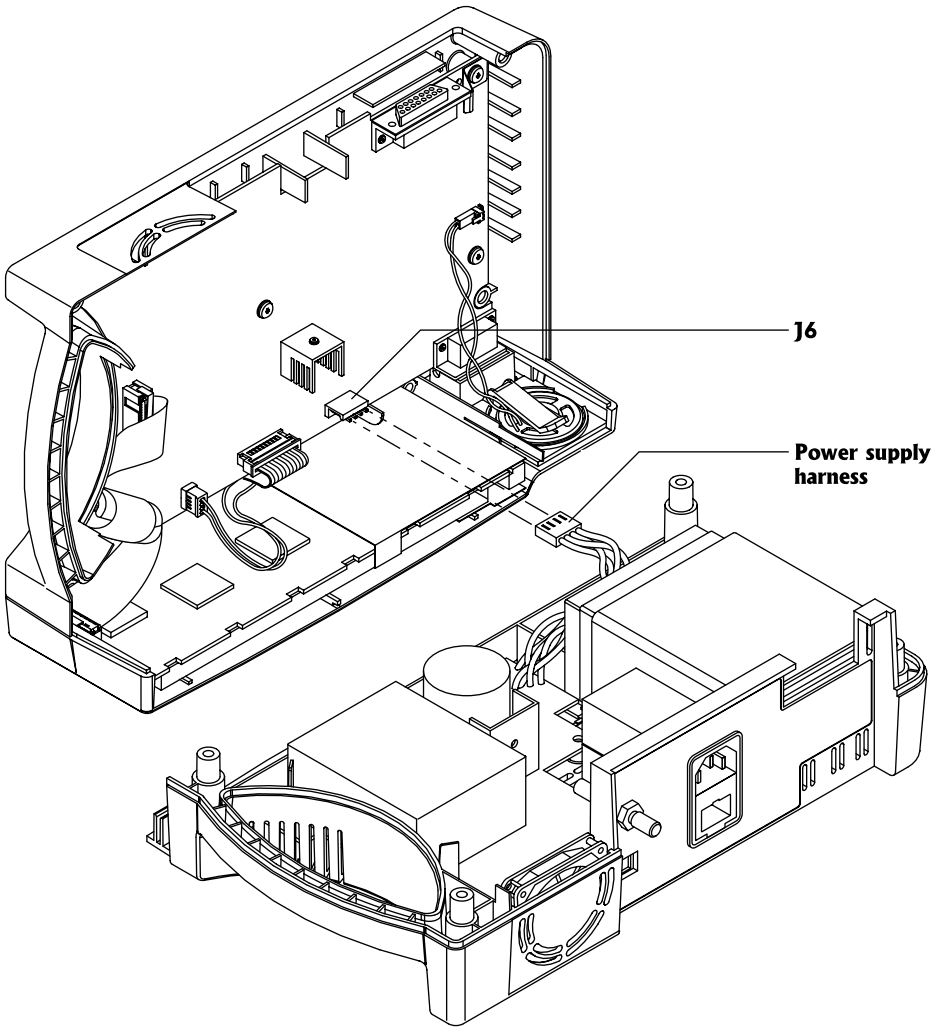


Figure 6-3: Separating Case Halves

6.5 MONITOR REASSEMBLY

1. Connect the Power Supply to J6 on the UIF PCB.
2. Place the top case over the bottom case, being careful to align the lens, Power Entry Module, and the fan with the slots in the top case.

Caution: When reassembling the NPB-195, tighten the screws that hold the cases together to a maximum of 10 inch-pounds. Over-tightening could strip out the screw holes in the top case, rendering it unusable.

3. Install the four corner screws.

6.6 BATTERY REPLACEMENT

Removal

1. Follow the procedure in paragraphs 6.2 and 6.4.
2. Remove the two screws from the battery bracket and lift the battery out of the bottom case as shown in Figure 6-4.
3. Be sure to note the polarity of the leads. Use needle-nose pliers to disconnect the leads from the battery.

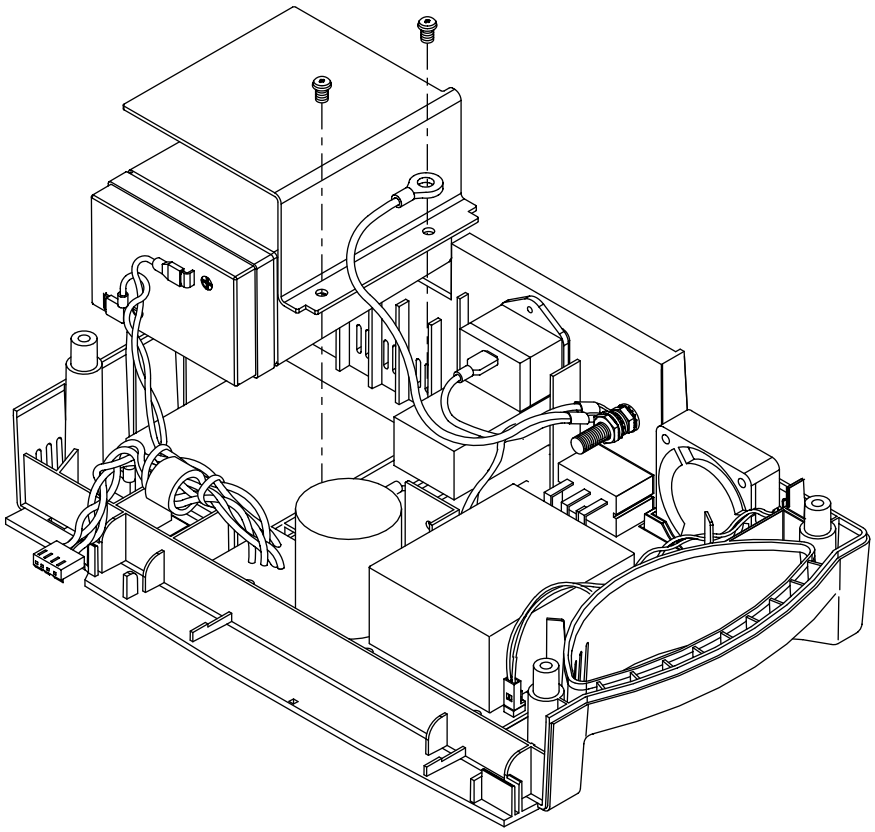


Figure 6-4: NPB-195 Battery

4. The lead-acid battery is recyclable. Do not dispose of the battery by placing it in the regular trash. Dispose of battery in accordance with local regulations or return to Mallinckrodt's Technical Services Department for disposal.

Installation

5. Connect the leads to the battery. The red wire connects to the positive terminal, and the black wire connects to the negative terminal. See Figure 6-5.
6. Insert the new battery into the bottom case with the negative terminal towards the outside of the monitor. Install the bracket and grounding lead with the two screws.

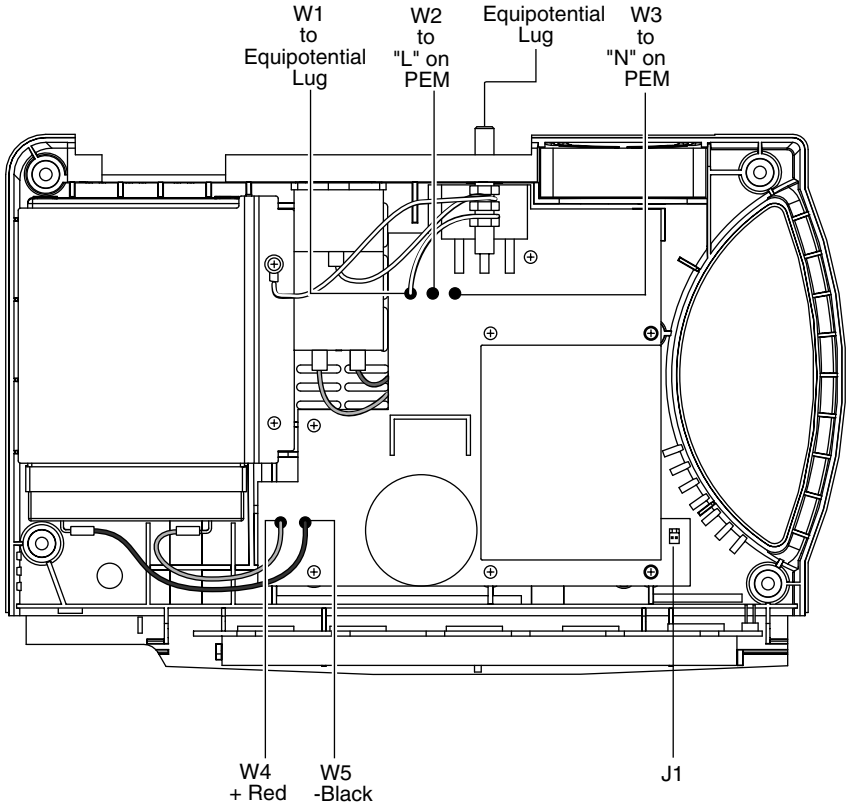


Figure 6-5: Internal Power Connections

7. Complete the procedure in paragraph 6.5.
8. Turn the monitor on and verify proper operation.

6.7 POWER ENTRY MODULE (PEM) REMOVAL/INSTALLATION

Removal

1. Complete the procedures in paragraphs 6.4.
2. Push the top of the Power Entry Module (PEM) in from the outside of the case, and lift up.
3. Use needle-nose pliers to disconnect the leads from the PEM (see Figure 6-6).

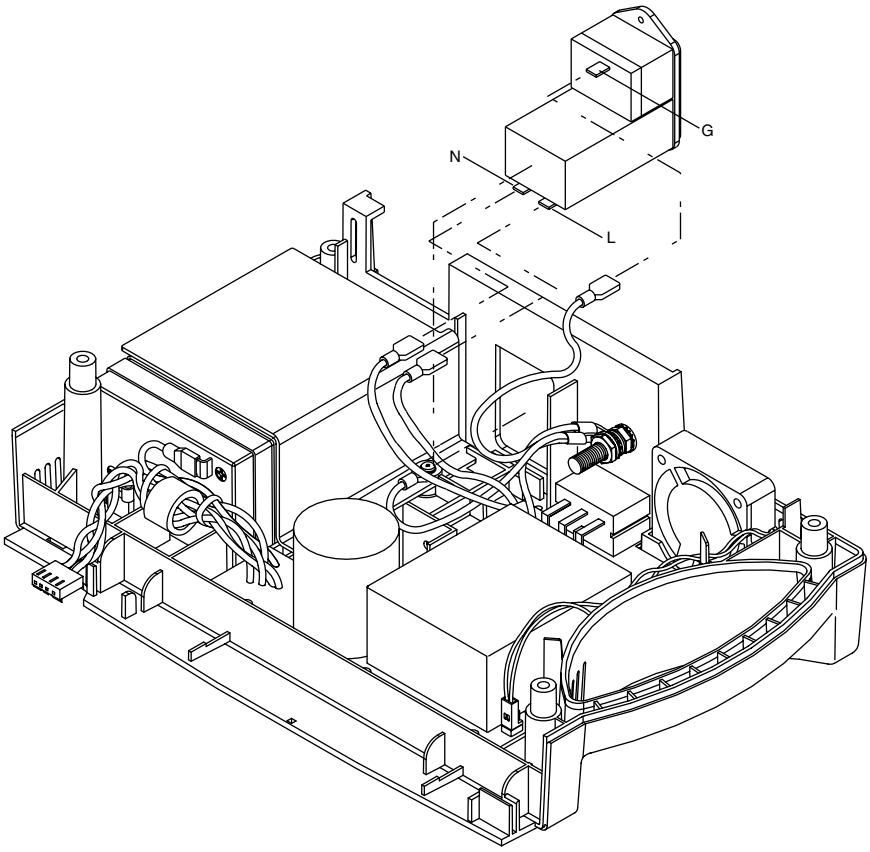


Figure 6-6: Power Entry Module

Installation

4. Reconnect the three leads. The blue wire from W3 on the power supply goes to the terminal labeled “N” on the PEM. The brown wire from W2 on the power supply connects to the terminal labeled “L.” The center terminal (labeled "G") at the top of the PEM is for the ground wire (Figure 6-6).
5. Install the PEM in the bottom case with the fuse drawer facing down. A tab in the bottom case holds the PEM in place. Insert the bottom wing of the PEM between the tab and the internal edge of the side wall of the bottom case. Push the PEM down and towards the outside of the monitor until it clicks into place.

6. Position the AC lines from the PEM so that they do not come into contact with components on the Power Supply PCB.

7. Complete procedure in paragraph 6.5.

6.8 POWER SUPPLY REMOVAL/INSTALLATION

Removal

1. Complete the procedures in paragraphs 6.2 and 6.4.

2. Complete steps 2 through 4 in paragraph 6.7.

3. Disconnect the fan wire harness from J1 on the Power Supply PCB (see Figure 6-5).

4. Use a 10-mm wrench to disconnect the Power Supply ground lead from the equipotential lug (Figure 6-5).

5. Remove the seven screws shown in Figure 6-7.

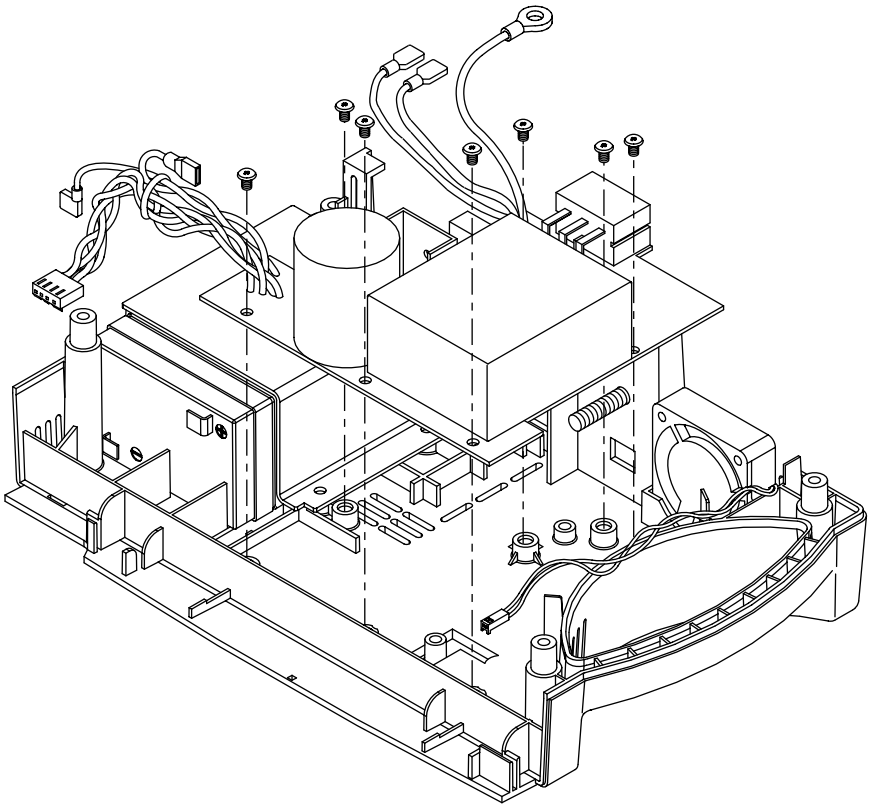


Figure 6-7: Power Supply

6. Lift the Power Supply out of the bottom case.

Installation

7. Place the Power Supply in the bottom case.

Caution: When installing the Power Supply, tighten the seven screws to a maximum of 4 inch-pounds. Over-tightening could strip out the screw holes in the bottom case, rendering it unusable.

8. Install the seven screws in the Power Supply and tighten.
9. Connect the fan harness to J1 on the Power Supply.
10. Complete steps 4 through 6 in paragraph 6.7.
11. Complete procedure in paragraph 6.5.

6.9 COOLING FAN REMOVAL/INSTALLATION

Removal

1. Complete the procedures in paragraphs 6.2 and 6.4.
2. Disconnect the fan wire harness from J1 on the Power Supply PCB (see Figure 6-5).
3. Lift the cooling fan from the slots in the bottom case (see Figure 6-8).

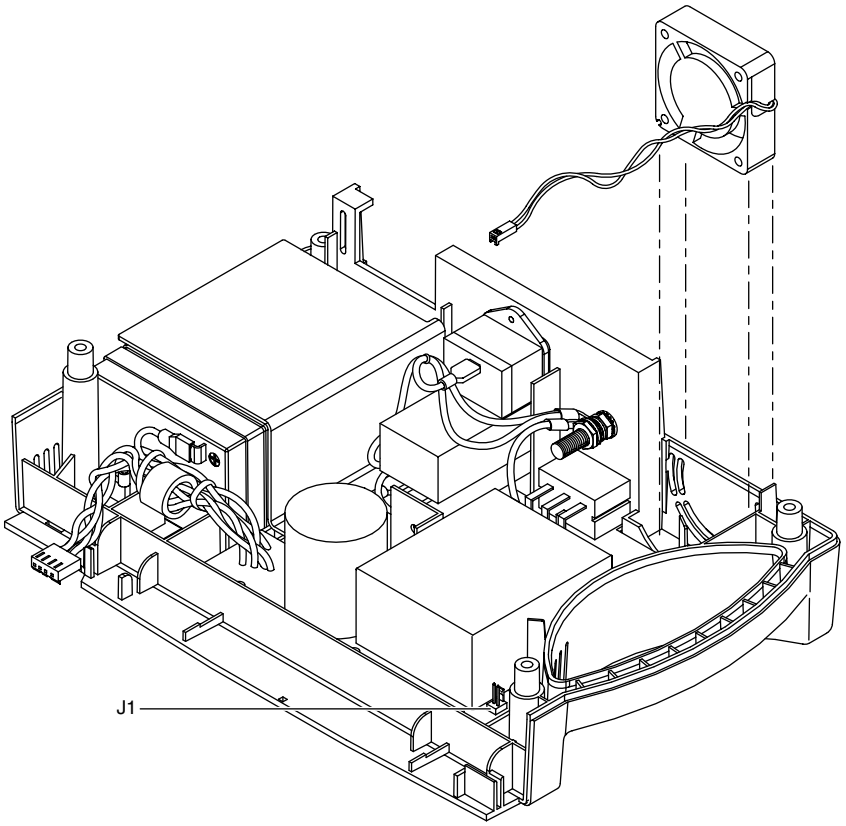


Figure 6-8: Cooling Fan

Installation

4. Insert the cooling fan into the slots in the bottom case with the padded sides on the top and bottom and the fan's harness to the handle side of the case.
5. Connect the cooling fan wire harness to J1 on the Power Supply PCB.
6. Complete procedure 6-5.

6.10 DISPLAY PCB REMOVAL/INSTALLATION

Removal

Note: The LCD panel contains toxic chemicals. Do not ingest chemicals from a broken LCD panel.

1. Complete procedures 6.2 and 6.4.
2. Disconnect the CCFL harness (two white wires) from J5 of the UIF PCB. See Figure 6-9.
3. Use a small blade screwdriver to pry the clip from either edge of J9, then disconnect the Display PCB ribbon cable from the connector.
4. Remove the screw holding the clamp to the ferrite on the ribbon cable of the Display PCB.

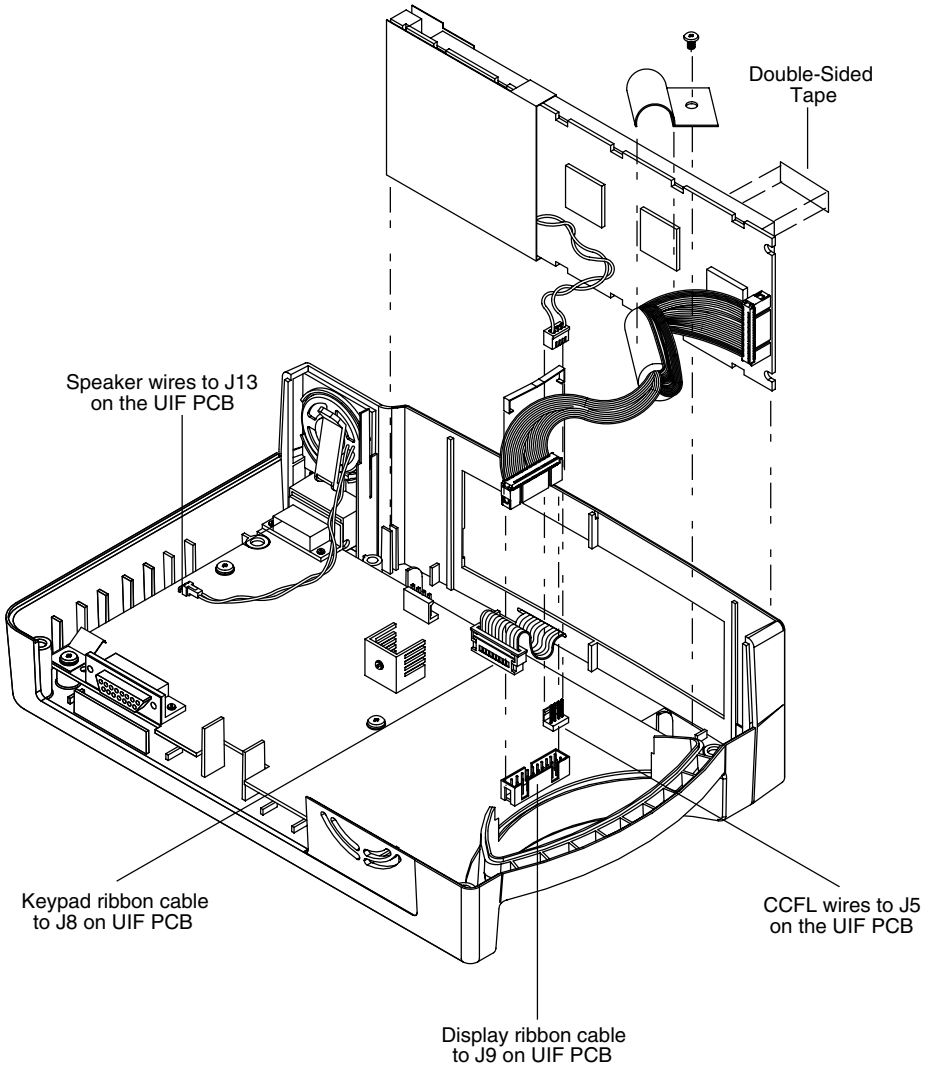

Double-Sided Tape
Speaker wires to J13 on the UIF PCB
Keypad ribbon cable to J8 on UIF PCB
CCFL wires to J5 on the UIF PCB
Display ribbon cable to J9 on UIF PCB

Figure 6-9: Display PCB

5. Separate the adhesive connection of the double-sided tape and lift the Display PCB up to remove it from the top case.
6. Remove the used double-sided tape.

Installation

7. Install new double-sided tape located as shown in Figure 6-9.
8. Slide the Display PCB into the grooves in the top case. Apply pressure between the top case and the display PCB to make good contact with the double-sided tape.
9. Connect the wire harness with two white wires to J5 of the UIF PCB.
10. Connect the Display PCB ribbon cable to J9 of the UIF PCB. Install the clip over the J9 connector.
11. Secure the ferrite on the ribbon cable from the Display PCB. Place the clamp over the ferrite and screw the clamp to the UIF PCB.
12. Complete the procedure in paragraph 6.5.

6.11 UIF PCB REMOVAL/INSTALLATION

Removal

1. Complete the procedures in paragraphs 6.2 and 6.4.
2. Complete steps 2 through 4 in paragraph 6.10.
3. Disconnect the keypad ribbon cable from J8 of the UIF PCB (Figure 6-9). J8 is a ZIF connector. Lift up on the outer shell until it clicks, then remove the ribbon cable from the connector.
4. Disconnect the speaker cable from J13 on the UIF PCB.
5. Remove the five screws in the UIF PCB. See Figure 6-10.
6. Remove the UIF PCB from the top case.

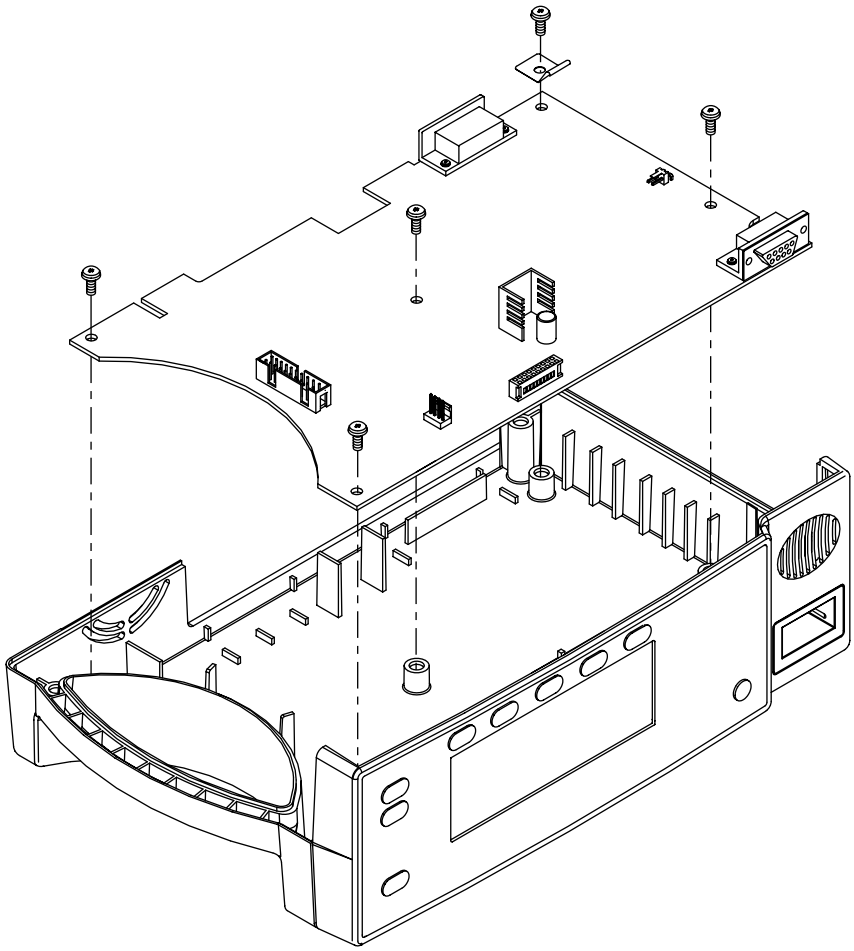


Figure 6-10: UIF PCB

Installation

Caution: When installing the UIF PCB, hand tighten the five screws to a maximum of 4 inch-pounds. Over-tightening could strip out the screw holes in the top case, rendering it unusable.

7. Place the UIF PCB in the top case.
8. Install the four screws in the UIF PCB.
9. Lift up on the outer shell of J8 on the UIF PCB until it clicks. Insert the keypad ribbon cable into J8 of the UIF PCB. Slide the outer shell of J8 down until it clicks.
10. Connect the speaker cable to J13 of the UIF PCB.
11. Complete steps 8 through 10 of procedure in paragraph 6.10.
12. Complete procedure in paragraph 6.5.

6.12 ALARM SPEAKER REMOVAL/INSTALLATION

Removal

1. Complete the procedures in paragraphs 6.2 and 6.4.
2. Disconnect the speaker wire harness from J13 on the UIF PCB (see Figure 6-11).
3. Pull the retaining tab back from the speaker and lift the speaker out of the top case.

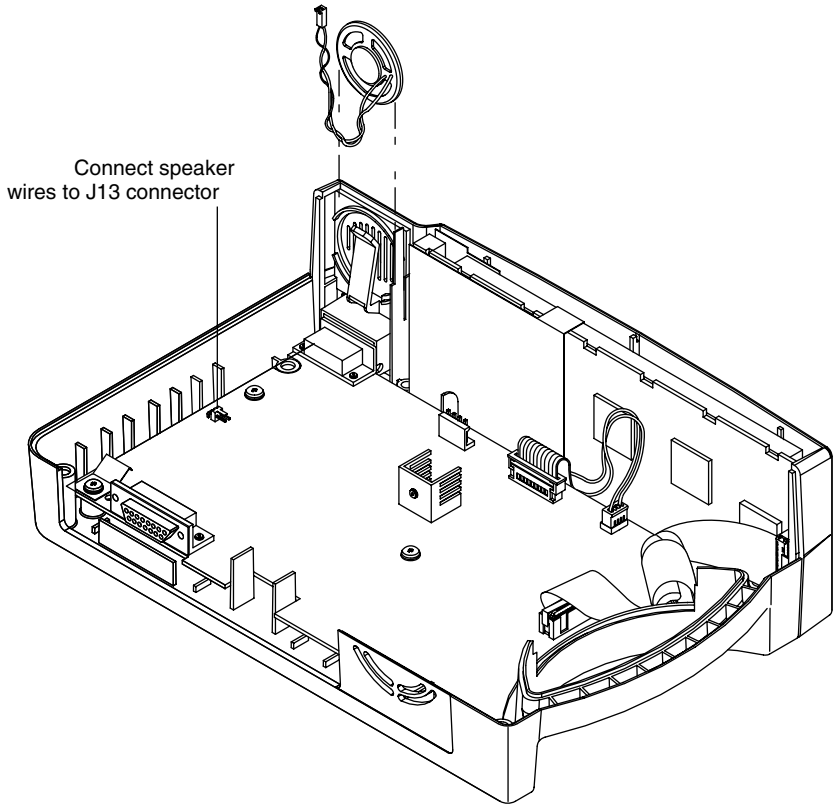


Figure 6-11: Alarm Speaker

Installation

4. Pull the retaining tab back and insert the speaker into the top case.
5. Connect speaker wire harness to J13 on the UIF PCB.
6. Complete the procedure in paragraph 6.5.

SECTION 7: SPARE PARTS

7.1 INTRODUCTION

Spare parts, along with part numbers, are shown in Table 7-1. Item numbers correspond to the callout numbers in Figure 7-1.

Table 7-1: Parts List

Item	Description	Part No.
1	Top Case Assembly (Membrane Panel Included)	048451
2	Fuse Drawer	691500
3	Fuses	691032
4	Power Entry Module	691499
5	Cooling Fan	035469
6	Power Supply	035200
7	LCD PCB	035403
8	Battery	640119
9	Battery Bracket	035307
10	UIF PCB	035263
	Sensor Lock (not shown)	022943
	Alarm Speaker (not shown)	033494
	Ground Clip (not shown)	035400
	Rubber Feet (not shown)	4-003818-00
	Power Cord (not shown)	U.S. 071505 International 901862 U.K. 901863

Figure 7-1 shows the NPB-195 expanded view with numbers relating to the spare parts list.

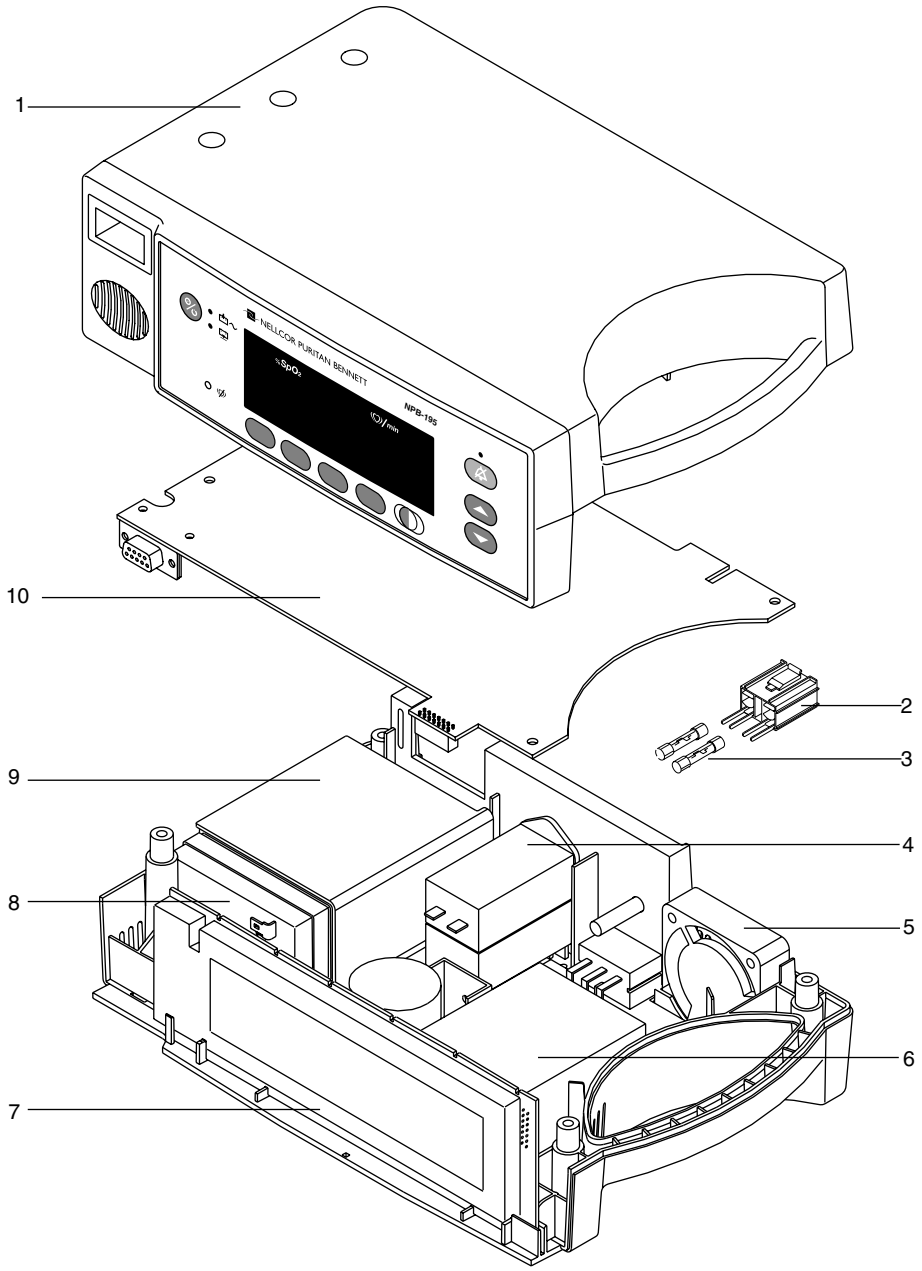


Figure 7-1: NPB-195 Expanded View

SECTION 8: PACKING FOR SHIPMENT

8.1 General Instructions
8.2 Repacking in Original Carton
8.3 Repacking in a Different Carton

To ship the monitor for any reason, follow the instructions in this section.

8.1 GENERAL INSTRUCTIONS

Pack the monitor carefully. Failure to follow the instructions in this section may result in loss or damage not covered by any applicable Mallinckrodt warranty. If the original shipping carton is not available, use another suitable carton; North American customers may call Mallinckrodt's Technical Services Department to obtain a shipping carton.

Prior to shipping the monitor, contact your supplier or the Mallinckrodt's Technical Services Department for a returned goods authorization (RGA) number. Mark the shipping carton and any shipping documents with the returned goods authorization number.

8.2 REPACKING IN ORIGINAL CARTON

If available, use the original carton and packing materials. Pack the monitor as follows:

1. Place the monitor and, if necessary, accessory items in original packaging.

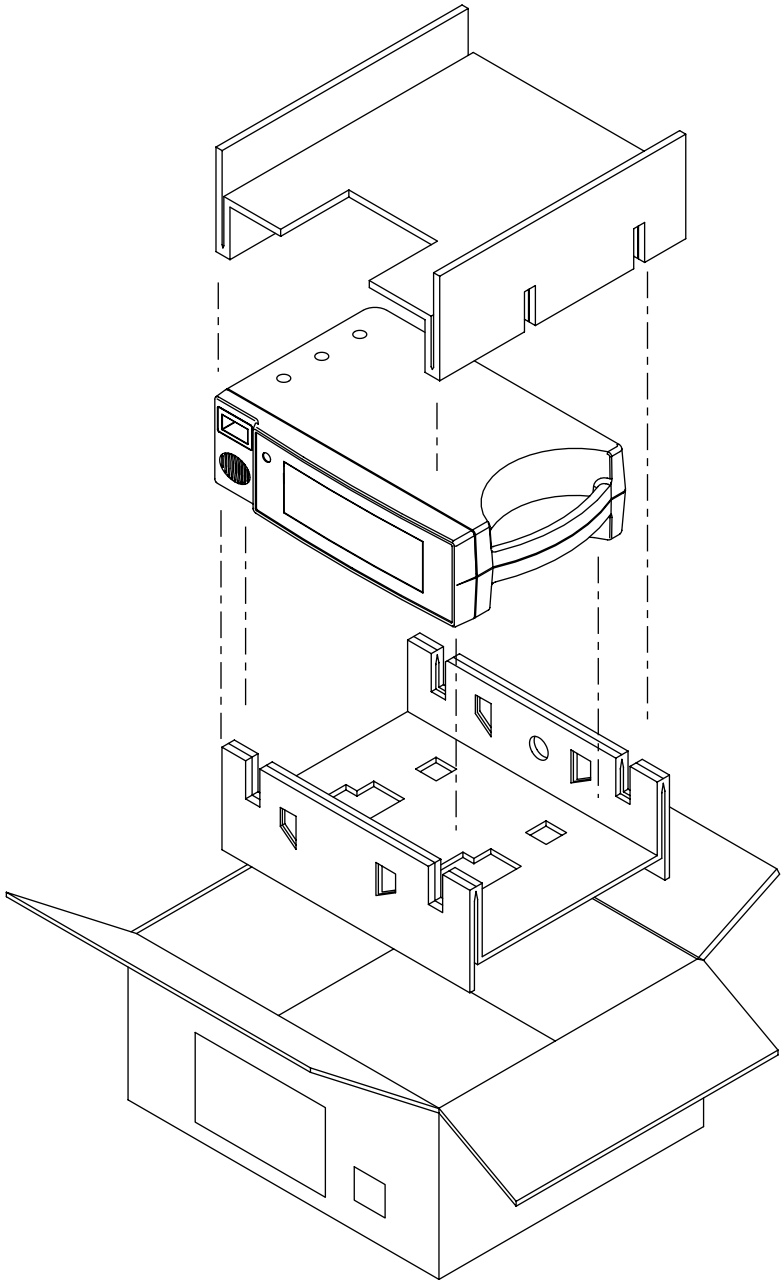


Figure 8-1: Repacking the NPB-195

2. Place in shipping carton and seal carton with packing tape.
3. Label carton with shipping address, return address and RGA number, if applicable.

8.3 REPACKING IN A DIFFERENT CARTON

If the original carton is not available, use the following procedure to pack the NPB-195:

1. Place the monitor in a plastic bag.
2. Locate a corrugated cardboard shipping carton with at least 200 pounds per square inch (psi) bursting strength.
3. Fill the bottom of the carton with at least 2 inches of packing material.
4. Place the bagged unit on the layer of packing material and fill the box completely with packing material.
5. Seal the carton with packing tape.
6. Label the carton with the shipping address, return address, and RGA number, if applicable.

SECTION 9: SPECIFICATIONS

9.1 General
9.2 Electrical
9.3 Physical Characteristics
9.4 Environmental
9.5 Alarms
9.6 Factory Default Settings
9.7 Performance

9.1 GENERAL

Designed to meet safety requirements of:

UL 2601-1 CSA-C22.2 No. 601-1-M90, IEC 601-1 (Class I, type BF), ISO 9919, EMC per EN 60601-1-2.

9.2 ELECTRICAL

9.2.1 Protection Class

Class I: per I.E.C. 601-1, clause 2.2.4

9.2.2 Degree of Protection

Type BF: per I.E.C. 601-1, clause 2.2.26

9.2.3 Mode of Operation

Continuous

9.2.4 Battery

Type:	Rechargeable sealed lead-acid, internal
Operating time:	6 hours minimum on new, fully charged battery with no backlight or alarms
Recharge period:	14 hours for full charge (in standby)
	18 hours for full charge (in use)

9.2.5 Fuses

2 each 5 x 20 mm

0.5 Amp 250 volts

9.2.6 AC Power

Selectable by switch	100-120 VAC 50/60 Hz or
	200-240 VAC 50/60 Hz

9.3 PHYSICAL CHARACTERISTICS

9.3.1 Dimensions

3.3 in. H x 10.4 in. W x 6.8 in. D

8.4 cm H x 26.4 cm W x 17.3 cm D

9.3.2 Weight

5.7 lbs

2.6 kg

9.4 ENVIRONMENTAL

9.4.1 Operating Temperature

5°C to 40°C (+41°F to +104°F)

9.4.2 Storage Temperature

-20°C to +70°C (-4°F to +158°F)

9.4.3 Operating Altitude

-390 m to +3,048 m (-1,280 ft. to +10,000 ft.)

9.4.4 Relative Humidity

15% RH to 95% RH, noncondensing

9.5 ALARMS

9.5.1 Alarm Limit Range

% Saturation:	20–100%
Pulse:	30–250 bpm

9.6 FACTORY DEFAULT SETTINGS

Table 9-1: Default Settings

Parameter	Default Value
SpO_2 High	100%
SpO_2 Low	85%
Pulse Rate High	170 bpm
Pulse Rate Low	40 bpm
Alarm Volume	Level 5
Alarm Silence Duration	60 seconds
Alarm Silence Restriction	Off with reminder
Pulse Beep Volume	Level 4
Baud Rate	9600
Display	Pleth
Trend	Saturation
Contrast	Mid-range
Language	English

9.7 PERFORMANCE

9.7.1 Measurement Range

SpO_2:	0–100%
Pulse/Heart Rate:	30–250 bpm

9.7.2 Accuracy[1]

9.7.2.1 SpO_2

Adult:	70–100% ± 2 digits
	0–69% unspecified
Neonatal:	70–100% ± 3 digits
	0–69% unspecified

9.7.2.2 Pulse Rate (optically derived)[2]

20–250 bpm ± 3 bpm

[1] Accuracies are expressed as plus or minus "X" digits (saturation percentage points) between saturations of 70-100%. This variation equals plus or minus one standard deviation (1 SD), which encompasses 68% of the population. All accuracy specifications are based on testing the subject monitor on healthy adult volunteers in induced hypoxia studies across the specified range. Adult accuracy is determined with *Oxisensor II* D-25 sensors. Neonatal accuracy is determined with *Oxisensor II* N-25 sensors.

[2] Accuracies are expressed as plus or minus "X" bpm across the display range. This variation equals plus or minus 1 Standard Deviation, which encompasses 68% of the population.

SECTION 10: SERIAL PORT INTERFACE PROTOCOL

10-1 Introduction
10-2 Enabling the Serial Port
10-3 Connecting to the Serial Port
10-4 Real-Time Printout
10-5 Trend Data Printout
10-6 Nurse Call

10.1 INTRODUCTION

When a printer is connected to the serial port on the back of the NPB-195, a real-time printout can be obtained. A new line of data is printed every 2 seconds. Column headings will be printed after every 25 lines or if one of the values in the column heading changes. Changing an alarm limit, for example, would cause a new column heading to be printed. Printouts include patient and device data. A real-time printout cannot be obtained if the unit is operating on battery power. The real-time printout is discussed in more detail in paragraph 10.4.

10.2 ENABLING THE SERIAL PORT

Real-Time data is constantly being sent to the serial port of the NPB-195. To receive a real-time printout, see paragraph 10.3, for instructions to make the connection.

The baud rate may need to be changed to match the abilities of the attached equipment. To change the baud rate, press the Setup softkey, then the Comm softkey. Use the Adjust Up/Down buttons to select a baud rate of 2400, 9600, or 19200.

10.3 CONNECTING TO THE SERIAL PORT

Data is transmitted in the standard RS-232 format. Only three lines are used: GND is the ground, TxD represents the Transmit Data Line, and RxD is the Receive Data Line. No hardware flow control is used. However, XON/XOFF flow control is supported. Pin-outs for the serial port are listed in the chart below.

Table 10-1: Serial Port Pin-Outs

Pin	Line
2	RxD
3	TxD
5, 10	GND
11	Nurse call
1, 4, 6-9, 12-15	No Connection

The pin layouts are illustrated in Figure 10-1. The conductive shell is used as earth ground. An AMP connector is used to connect to the serial port. Use AMP connector (AMP p/n 747538-1), ferrule (AMP p/n 1-747579-2), and compatible pins (AMP p/n 66570-2).

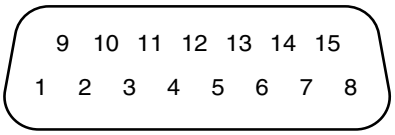


Figure 10-1: Serial Port Pin Layout

The serial cable can be a maximum of 25 feet and must be shielded. Connectors at both ends of the serial cable must have the shield terminated to the full 360 degrees of the connector's metal shell. If sharp bends in the cable or rough handling is anticipated, use a braided shield.

10.4 REAL-TIME PRINTOUT

When a Real-Time display or printout is being transmitted to a printer or PC, a new line of data is printed every 2 seconds. Every 25th line is a Column Heading line. A column heading line is also printed any time a value in the column heading line is changed. A real-time printout is shown below in Figure 10-2.

Note: If the serial output stops transmitting, turn the power off and back on again or, if connected to a PC, send an XON (Ctrl-9) to reset the monitor.

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit:	30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status	
01-Jul-97 14:00:00	100	120	220		
01-Jul-97 14:00:02	100	124	220		
01-Jul-97 14:00:04	100	190	220		
01-Jul-97 14:00:06	100	190*	220	PH	
01-Jul-97 14:00:08	100	190*	220	PH	
01-Jul-97 14:00:10	100	190*	220	PH	
01-Jul-97 14:00:12	100	190*	220	PH	
01-Jul-97 14:00:14	100	190*	220	PH	
01-Jul-97 14:00:16	100	190*	220	PH LB	
01-Jul-97 14:00:18	100	190*	220	PH LB	
01-Jul-97 14:00:20	100	190*	220	PH LB	
01-Jul-97 14:00:22	- - -	- - -	- - -	SD LB	
01-Jul-97 14:00:24	- - -	- - -	- - -	SD LB	
01-Jul-97 14:00:26	- - -	- - -	- - -	SD	
01-Jul-97 14:00:28	- - -	- - -	- - -	SD	
01-Jul-97 14:00:30	- - -	- - -	- - -	SD	
01-Jul-97 14:00:32	- - -	- - -	- - -	SD	
01-Jul-97 14:00:34	- - -	- - -	- - -	PS	
01-Jul-97 14:00:36	- - -	- - -	- - -	PS	
01-Jul-97 14:00:38	- - -	- - -	- - -	PS	
01-Jul-97 14:00:40	- - -	- - -	- - -	PS	
01-Jul-97 14:00:42	- - -	- - -	- - -	PS	
01-Jul-97 14:00:44	- - -	- - -	- - -	PS	
NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit:	30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status	
01-Jul-97 14:00:46	- - -	- - -	- - -	PS	
NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit:	80-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status	
01-Jul-97 14:00:48	79*	59*	220	SL PL LB	
01-Jul-97 14:00:50	79*	59*	- - -	PS SL PL LB	

Figure 10-2: Real-Time Printout

10.4.1 Column Heading

To explain the printout it will be necessary to break it down to its key components. The first two lines of the chart are the Column Heading shown below. Every 25th line is a Column Heading. A column heading is also printed whenever a value of the Column Heading is changed. There are three Column Heading lines shown in Figure 10-2. Using the top row as the starting point, there are 25 lines before the second Column Heading is printed. The third Column Heading was printed because the SpO_2 limits changed from 30-100% to 80-100%.

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit:	30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status	

10.4.1.1 Data Source

NPB-195	VERSION 1.0.0.1	CRC XXXX	SpO2 Limit:	30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status	

Data in the highlighted box above represents the source of the printout or display, in this case the NPB-195.

10.4.1.2 Software Revision Level

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit:	30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status	

The next data field tells the user the software level (Version 1.0.0) and a software verification number (CRC XXXX). Neither of these numbers should change during normal operation. The numbers will change if the monitor is serviced and receives a software upgrade.

10.4.1.3 Alarm Limits

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit:	30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status	

The last data field in the top line indicates the high and the low alarm limits for $\%SpO_2$ and for the pulse rate (PR). In the example above, the low alarm limit for SpO_2 is 30% and the high alarm limit is 100%. Pulse Rate alarm limits are low 100 bpm, and high 180 bpm.

10.4.1.4 Column Headings

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit:	30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status	

Actual column headings are in the second row of the Column Heading line. Patient data that is presented in the chart, from left to right, is the time that the line was obtained, the current $\%SpO_2$ value being measured, the current Pulse Rate in beats per minute (bpm), the current Pulse Amplitude (PA), and the operating status of the NPB-195.

10.4.2 Patient Data and Operating Status

10.4.2.1 Time

TIME	%SpO2	BPM	PA	Status
01-Jul-97 14:00:00	100	120	220	

The Time column represents the NPB-195 real-time clock.

10.4.2.2 Patient Data

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit:	30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status	
01-Jul-97 14:00:06	100	190*	220	PH	

Patient data and the operating status of the unit are highlighted in the display above. Parameter values are displayed directly beneath the heading for each parameter. In this example the %SpO_2 is 100, and the pulse rate PR is 190 beats per minute. The "*" next to the 190 indicates that 190 beats per minute is outside of the alarm limits, indicated in the top row, for pulse rate. If no data for a parameter is available, three dashes (- - -) will be displayed in the printout.

PA is an indication of pulse amplitude. The number can range from 0 to 254. There are no alarm parameters for this value. It can be used for trending information. It is an indication of a change in pulse volume, pulse strength or circulation.

10.4.2.3 Status

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit:	30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status	
01-Jul-97 14:00:06	100	190*	220	PH	

The Status column indicates alarm conditions and operating status of the NPB-195. In this example the PH means Pulse High. A complete listing of the status codes is listed in Table 10-2. As many as 4 codes can be displayed at one time in the Status column.

Table 10-2: Status Codes

Code	Meaning
BU	**B**attery in **U**se
LB	**L**ow **B**attery
AS	**A**larm **S**ilence
AO	**A**larm **O**ff
SD	**S**ensor **D**isconnect
PS	**P**ulse **S**earch
LP	**L**oss of **P**ulse
SH	**S**at **H**igh Limit Alarm
SL	**S**at **L**ow Limit Alarm
PH	**P**ulse Rate **H**igh Limit Alarm
PL	**P**ulse Rate **L**ow Limit Alarm
- - -	No Data Available
*	Alarm Parameter Being Violated

Note: A Sensor Disconnect will also cause three dashes (- - -) to be displayed in the patient data section of the printout.

10.5 TREND DATA PRINTOUT

The format of data displayed when a trend printout is requested is similar to that of the real-time data. The only differences are that "TREND" is displayed in the top row instead of the "CRC:XXXX" software verification number, and there is no "Status" column.

Readings are displayed in 5-second intervals. The values on each row are an average for the 5-second period.

At the end of the printout, an "Output Complete" line indicates that the transmission was successful. If the "Outlet Complete" line is not present, ignore the data.

NPB-195	VERSION 1.0.0.1		CRC: XXXX	SpO2 Limit:	30-100%	PR Limit: 100-180 bpm
TIME		%SpO2	PR (bpm)	PA		
22-Nov-97	14:00:05	100	120	150		
22-Nov-97	14:00:10	100	121	154		
22-Nov-97	14:00:15	100	120	150		
Output Complete						

Figure 10-3: Trend Data Printout

10.6 NURSE CALL

A nurse call signal can be obtained by connecting to the serial port. This function is available only when the instrument is operating on AC power. Nurse call will be disabled when the unit is operating on battery power.

The remote location will be signaled anytime there is an audible alarm. If the audible alarm has been turned off, or silenced, the nurse call function is also turned off.

Pin 11 on the serial port is the nurse call signal and pin 10 is ground (see Figure 10-1). When there is no alarm condition, the voltage between pins 10 and 11 will be -5 to -12 VDC. Whenever the monitor is in an alarm condition, the output between pins 10 and 11 will be +5 to +12 VDC.

SECTION 11: TECHNICAL SUPPLEMENT

11-1 Introduction
11-2 Oximetry Overview
11-3 Circuit Analysis
11-4 Functional Overview
11-5 AC Input
11-6 Power Supply Theory of Operation
11-7 Battery
11-8 User Interface PCB (UIF)
11-9 Front Panel Display PCB and Controls
11-10 Schematic Diagrams

11.1 INTRODUCTION

This Technical Supplement provides the reader with a discussion of oximetry principles and a more in-depth discussion of NPB-195 circuits. Block and schematic diagrams support a functional overview and detailed circuit analysis. The schematic diagrams are located at the end of this supplement.

11.2 OXIMETRY OVERVIEW

The NPB-195 is based on the principles of spectrophotometry and optical plethysmography. Optical plethysmography uses light absorption technology to reproduce waveforms produced by pulsatile blood. The changes that occur in the absorption of light due to vascular bed changes are reproduced by the pulse oximeter as plethysmographic wave forms.

Spectrophotometry uses various wavelengths of light to qualitatively measure light absorption through given substances. Many times each second, the NPB-195 passes red and infrared light into the sensor site and determines absorption. The measurements that are taken during the arterial pulse, reflect absorption by arterial blood, nonpulsatile blood, and tissue. The measurements that are obtained between arterial pulses reflect absorption by nonpulsatile blood and tissue.

By correcting "during pulse" absorption for "between pulse" absorption, the NPB-195 determines red and infrared absorption by pulsatile arterial blood. Because oxyhemoglobin and deoxyhemoglobin differ in red and infrared absorption, this corrected measurement can be used to determine the percent of oxyhemoglobin in arterial blood: SpO_2 is the ratio of corrected absorption at each wavelength.

11.2.1 Functional Versus Fractional Saturation

The NPB-195 measures functional saturation, that is, oxygenated hemoglobin expressed as a percentage of the hemoglobin that is capable of transporting oxygen. It does not detect significant levels of dyshemoglobins. In contrast, some instruments such as the IL282 Co-oximeter measure fractional saturation, that is, oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including dyshemoglobins.

Consequently, before comparing NPB-195 measurements with those obtained by an instrument that measures fractional saturation, measurements must be converted as follows:

$$\text{functional saturation} = \text{fractional saturation} \times \frac{100}{100-(\%\ \text{carboxyhemoglobin} + \%\text{methemoglobin})}$$

11.2.2 Measured Versus Calculated Saturation

When saturation is calculated from a blood gas measurement of the partial pressure of arterial oxygen (PaO_2), the calculated value may differ from the NPB-195 SpO_2 measurement. This is because the calculated saturation may not have been corrected for the effects of variables that can shift the relationship between PaO_2 and saturation.

Figure 11-1 illustrates the effect that variations in pH, temperature, partial pressure of carbon dioxide (PCO_2), and concentrations of 2,3-DPG and fetal hemoglobin may have on the oxyhemoglobin dissociation curve.

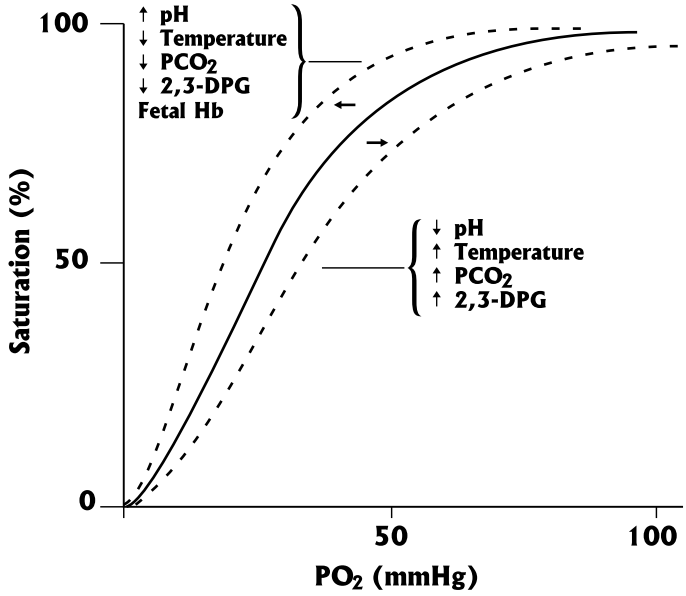


Figure 11-1: Oxyhemoglobin Dissociation Curve

11.3 CIRCUIT ANALYSIS

The following paragraphs discuss the operation of each of the printed circuit boards within the NPB-195 pulse oximeter. (Refer to the appropriate schematic diagram at the end of this supplement, as necessary.)

11.4 FUNCTIONAL OVERVIEW

The functional block diagram for the NPB-195 monitor is shown in Figure 11-2. Most of the functions of the NPB-195 are performed on the UIF PCB. Functions on the UIF PCB include the SpO_2 module, 331 and 196 CPUs, and Memory. Other key components of the NPB-195 are the Power Entry Module (PEM), Power Supply, and the LCD Display.

The Display module includes the Membrane Panel and the LCD Display. The Membrane panel contains enunciators and push buttons, allowing the user to access information and to select various available parameters. The LCD Display PCB contains the LCD that presents the patient data.

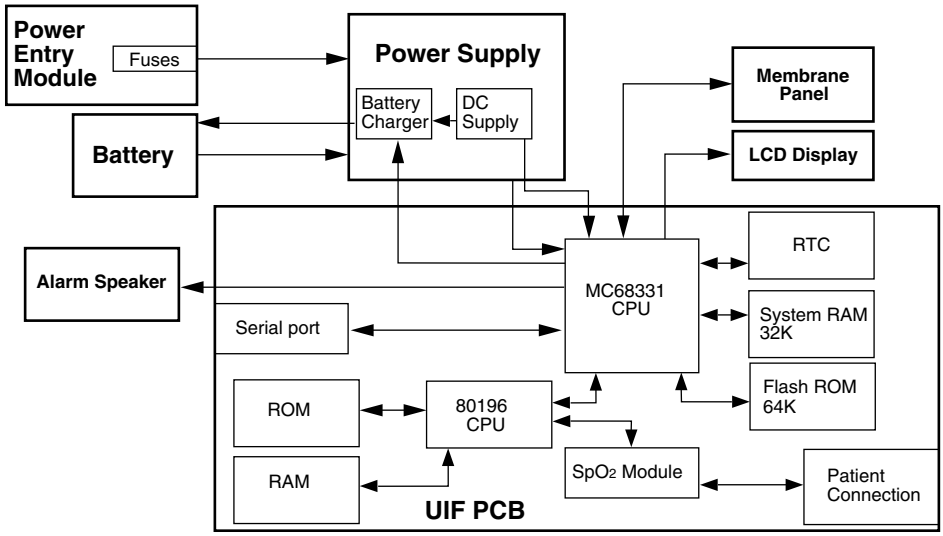


Figure 11-2: NPB-195 Functional Block Diagram

11.5 AC INPUT

A selector switch on the back of the NPB-195 allows the user to connect the monitor to AC power ranging from 100 VAC to 240 VAC. The switch has two positions, one for 100 VAC through 120 VAC and one for 210 VAC through 240 VAC. Verify that the switch selection matches the AC power at your location before plugging the monitor into an AC outlet.

AC power enters the NPB-195 through the Power Entry Module (PEM). A 0.5-amp fuse is placed in both the "Hot" and "Neutral" lines. These user accessible fuses are located in a fuse drawer, which is part of the PEM on the back of the instrument.

11.6 POWER SUPPLY PCB THEORY OF OPERATION

The NPB-195 uses an unregulated linear power supply. This power supply provides the DC power needed to charge the battery, run the cooling fan and to power the User Interface PCB (UIF). Electro Static Discharge (ESD) protection is also provided by the power supply.

AC power from the PEM is passed through a step-down transformer, T2, which has two primary and two secondary windings. If switch SW1 on the back of the monitor is in the 120 VAC position, the primary windings are in parallel. The primary windings are in series if SW1 is in the 240 VAC position.

Each secondary winding is fused with a 2.0 amp fuse (F1 and F2). If a short circuit should occur in the DC circuitry, these fuses prevent the transformer from overheating. The output of the transformer varies, depending on load and input. Voltage measured between the outlet of a secondary winding and ground can be from 6 to 20 VAC. C6 and C8 filter high frequency noise from the AC line and from the UIF PCB before passing through the bridge rectifier.

Two outputs from the bridge rectifier are used in the NPB-195. The fan control circuit uses the negative output. The positive output is the Main DC ranging from 7 to 18 VDC. This positive voltage is used for the battery circuit and to power the UIF PCB.

11.6.1 Fan Control

A fan control circuit on the Power Supply PCB is used to control the temperature inside the case of the NPB-195. The temperature sensor used in this circuit is U3. U3 turns on the cooling fan if the temperature inside the case gets above approximately 31° C. The cooling fan runs on approximately 15 VDC.

Note: The fan is disabled if the unit is running on battery power.

11.6.2 Battery Circuits

Two circuits are included in this section of the Power Supply PCB. One circuit is used to charge the battery and the other circuit provides battery protection.

11.6.2.1 Charging Circuit

The power supply will charge the battery any time the NPB-195 is connected to AC power even if the monitor is not turned on. The voltage applied to the battery is 6.8 ± 0.15 VDC and is current limited to 400 ± 80 mA.

Battery voltage is checked periodically by the processor. A signal from the processor turns the charging circuit off to allow this measurement to be taken. If the processor determines the battery voltage is below 5.85 ± 0.1 VDC, a low battery alarm is declared.

11.6.2.2 Battery Protection

Two types of battery protection are provided by the power supply: protection for the battery and protection from the battery.

SW2 is a resettable component that protects the battery. SW2 opens and turns the charging circuit off if the temperature of the battery rises above 50° C. If the output of the battery exceeds 2.0 amps, F3 opens. F3 protects the battery from a short to ground of the battery output.

Protection from the battery is provided in the event of the battery being connected backwards. Components on the UIF PCB and the Power Supply block and limit the voltage, to provide protection to circuits in the instrument.

11.7 BATTERY

A lead-acid battery is used in the NPB-195. It is rated at 6 VDC 4 amp-hours. When new and fully charged, the battery will operate the monitor for 6 hours with no backlight or alarms. The battery can withstand 400 charge/discharge cycles. Recharging the battery to full capacity will take 14 hours in standby or 18 hours if the instrument is being used.

Changeover from AC to battery power will not interrupt the normal monitoring operation of the NPB-195. However, when the unit is running on battery power, the cooling fan, serial port, nurse call, and LCD backlight will be turned off.

The 331 CPU on the UIF PCB monitors the charge level of the battery. If the voltage of the battery falls below 5.85 ± 0.1 VDC, a low battery alarm is declared. The instrument will continue monitoring and alarming for 15 minutes then power down. This 15-minute alarm and power-down sequence can be repeated by turning the unit back on, provided the battery voltage remains above the critical level.

Battery voltage is considered critical when it decreases to 5.67 ± 0.1 DCV. If the instrument is turned on and battery voltage is at the critical level, an error code is displayed and the instrument will not monitor the patient. The instrument will run for 15 minutes with the error code displayed and then power down.

Both conditions can be corrected by plugging the unit into an AC source for 14 hours to allow the battery to fully recharge.

11.8 USER INTERFACE PCB (UIF)

The UIF PCB is the heart of the NPB-195. All functions except the unregulated DC power supply, LCD display and membrane keypad reside on the UIF PCB.

11.8.1 Regulated DC Power Supply

The UIF PCB receives the Main_DC unregulated voltage of 7 to 18 VDC from the Power Supply or 5.8 to 6.5 VDC from the internal battery. From either of these signals, the regulated power supply on the UIF PCB generates +10.0, -10.0, -5.0 and +5.0 VDC.

11.8.2 Controlling Hardware

Two microprocessors reside on the UIF PCB. The CPU is an MC68331CF (331). The CPU controls the second microprocessor, an Intel 80C196KC (196).

11.8.2.1 CPU

The 331 is the main controller of the NPB-195. The 331 controls the front panel display, data storage, instrument status, serial port communication, and nurse call. The 331 monitors all buttons on the user interface.

The user interface includes the front panel display and the keypad. By pressing any of the keys on the keypad, the operator can access different functions of the NPB-195. The 331 will recognize the keystroke and make the appropriate change to the monitor. Some of the changes operators can make include the view on the LCD display, alarm limits, and alarm volume. SECTION 4: of this manual goes into more detail about the use of the softkeys.

Patient data is stored by the NPB-195 and can be downloaded to a printer through the serial port provided on the back of the instrument. An in-depth discussion of the serial port is covered in the Section 10 of this manual.

Power to the NPB-195 is monitored by the 331, which will determine if the instrument is running on AC, or on battery power. If the monitor is running on AC power, the 331 will periodically turn off the battery charge circuit to check the battery charge level.

When the 331 sends a signal to the alarm speaker, three items are used to determine the tone that is sent. First, pulse tones change with the %SpO_2 value being measured. The pulse beep tone will rise and fall with the measured %SpO_2. Second, three levels of alarms, each with its own tone, can occur: High, Medium and Low priority. Third, the volume of the alarm is user adjustable. Alarm volume can be adjusted from 1 to level 10, with level 10 being the highest volume.

When AC powers the NPB-195, the nurse call function is available. If no audible alarms are occurring, the output from the serial port (- pin 10, + pin 11) will be from minus 3 to minus 10 VDC. When there is an audible alarm (not silenced or disabled) the output will be positive 3 to positive 10 VDC.

11.8.2.2 196

Primary responsibilities of the 196 include controlling the SpO_2 function and communicating data to the 331.

A pulse width modulator (PWM) function built into the 196 controls the SpO_2 function. PWM signals are sent to control the intensity of the LEDs in the sensor. The gain of amplifiers receiving return signals from the photodetector in the sensor are also controlled by PWM signals.

Analog signals are received from the SpO_2 circuit on the UIF PCB. An Analog to Digital (A/D) function in the 196 converts these signals to the digital values for %SpO_2 and heart rate. These values are then sent to the 331 to be displayed and stored.

11.8.3 Sensor Output/LED Control

The SpO_2 analog circuitry provides control of the red and IR LEDs such that the received signals are within the dynamic range of the input amplifier. Because excessive current to the LEDs will induce changes in their spectral output, it is sometimes necessary to increase the received signal channel gain. To that point, the CPU controls both the current to the LEDs and the amplification in the signal channel.

At initialization of transmission, the LEDs' intensity level is based on previous running conditions, and the transmission intensity is adjusted until the received signals match the range of the A/D converter. If the LEDs reach maximum output without the necessary signal strength, the PWMs will increase the channel gain. The PWM lines will select either a change in the LED current or signal gain, but will not do both simultaneously.

The LED drive circuit switches between red and IR transmission and disables both for a time between transmissions in order to provide a no-transmission reference. To prevent excessive heat build-up and prolong battery life, each LED is on for only a small portion of the duty cycle. Also, the frequency of switching is well above that of motion artifact and not a harmonic of known AC transmissions. The LED switching frequency is 1.485 kHz. The IR transmission alone, and the red transmission alone, will each be on for about one-fifth of the duty cycle; this cycle is controlled by the 196.

11.8.4 Input Conditioning

Input to the SpO_2 analog circuit is the current output of the sensor photodiode. In order to condition the signal current, it is necessary to convert the current to voltage.

Because the IR and red signals are absorbed differently by body tissue, their received signal intensities are at different levels. Therefore, the IR and red signals must be demodulated and then amplified separately in order to compare them to each other. De-multiplexing is accomplished by means of two circuits that alternately select the IR and red signal. Two switches that are coordinated with the IR and red transmissions control selection of the circuits. A filter with a large time-constant follows to smooth the signal and remove noise before amplification.

11.8.5 Signal Gain

The separated IR and red signals are amplified so that their DC values are within the range of the A/D converter. Because the received IR and red signals are typically at different current levels, the signal gain circuits provide independent amplification for each signal as needed. The gain in these circuits is adjusted by means of the PWM lines from the CPU.

After the IR and red signals are amplified, they are filtered to improve the signal-to-noise ratio and clamped to a reference voltage to prevent the combined AC and DC signal from exceeding an acceptable input voltage from the A/D converter.

11.8.6 Variable Gain Circuits

The two variable gain circuits are functionally equivalent. The gain of each circuit is contingent upon the signal's received level and is controlled to bring each signal to approximately 3.5 V. Each circuit uses an amplifier and one switch in the triple SPDT analog-multiplexing unit.

11.8.7 AC Ranging

In order to achieve a specified level of oxygen saturation measurement and to still use a standard-type combined CPU and A/D converter, the DC offset is subtracted from each signal. The DC offsets are subtracted by using an analog switch to set the mean signal value to the mean of the range of the A/D converter whenever necessary. The AC modulation is then superimposed upon that DC level. This is also known as AC ranging.

Each AC signal is subsequently amplified such that its peak-to-peak values span one-fifth of the range of the A/D converter. The amplified AC signals are then filtered to remove the residual effects of the PWM modulations and, finally, are input to the CPU. The combined AC and DC signals for both IR and red signals are separately input to the A/D converter.

11.8.8 Real-Time Clock (RTC)

Real time is tracked by the NPB-195. As long as battery power or AC power is available, the instrument will keep time. If the battery is removed, the time clock will have to be reset.

The LCD will display real time when trends are selected. A time stamp is printed for each line of data on a printout. Real-time data is displayed and printed as Day, Month, Year, Hours, Minutes, and Seconds.

11.8.9 Patient Data Storage

Patient data is stored once every 5 seconds. A maximum of 24 hours of patient data can be stored. Up to 50 alarm limit changes can be retained. Trend data will be retained for a minimum of 30 days.

If battery power is disconnected or depleted, patient data will be lost. Data is stored with error detection coding. If data stored in memory is corrupted, it is discarded.

11.9 FRONT PANEL DISPLAY PCB AND CONTROLS

11.9.1 Display PCB

The Front Panel LCD display PCB displays patient data and status of the monitor.

At power up, all indicators and pixels are illuminated to allow verification of their proper operation. Next, the NPB logo and the software revision level are displayed. After this cycle has been completed the instrument is ready to begin monitoring.

The LCD allows the user to select among several different types of displays. Graphs, which are used for trend screens, can be displayed. Real-time patient data can include a plethysmographic waveform and digital values for SpO_2 and BPM. If a plethysmograph is not desired, the operator can select to view only digital data for SpO_2 and BPM along with a blip bar to show pulse intensity.

11.9.2 Membrane Keypad

A membrane keypad is mounted as part of the top case. A ribbon cable from the keypad passes through the top case and connects to the UIF PCB. Nine keys allow the operator to access different functions of the NPB-195.

These keys allow the user to select and adjust the alarm limits, cycle power to the unit, and to silence the alarm. Alarm volume and alarm silence duration can also be adjusted via the keypad. Pressing the softkeys can access a number of other functions. These functions are discussed in greater detail in Section 4.

Four LEDs are also part of the membrane keypad. These LEDs indicate AC power available, low battery, pulse search, and alarm silence.

11.10 SCHEMATIC DIAGRAMS

The following part locator diagrams and schematics are included in this section:

Figure 11-3: UIF PCB Front End Red/IR Schematic Diagram

Figure 11-4: Front End LED Drive Schematic Diagram

Figure 11-5: Front End Output Schematic Diagram

Figure 11-6: Front End Power Supply Schematic Diagram

Figure 11-7: Isolation Barrier EIA-232 Port Schematic Diagram

Figure 11-8: CPU Core Schematic Diagram A
Figure 11-9: CPU Core Schematic Diagram B
Figure 11-10: MC331 CPU Core Schematic Diagram A
Figure 11-11: MC331 CPU Core Schematic Diagram B
Figure 11-12: Display Driver Schematic Diagram
Figure 11-13: Speaker Driver Schematic Diagram
Figure 11-14: Core Power Supply Schematic Diagram
Figure 11-15: Power On/Off Circuit Schematic Diagram
Figure 11-16: UIF PCB Parts Locator Diagram
Figure 11-17: Power Supply Schematic Diagram
Figure 11-18: Power Supply Parts Locator Diagram

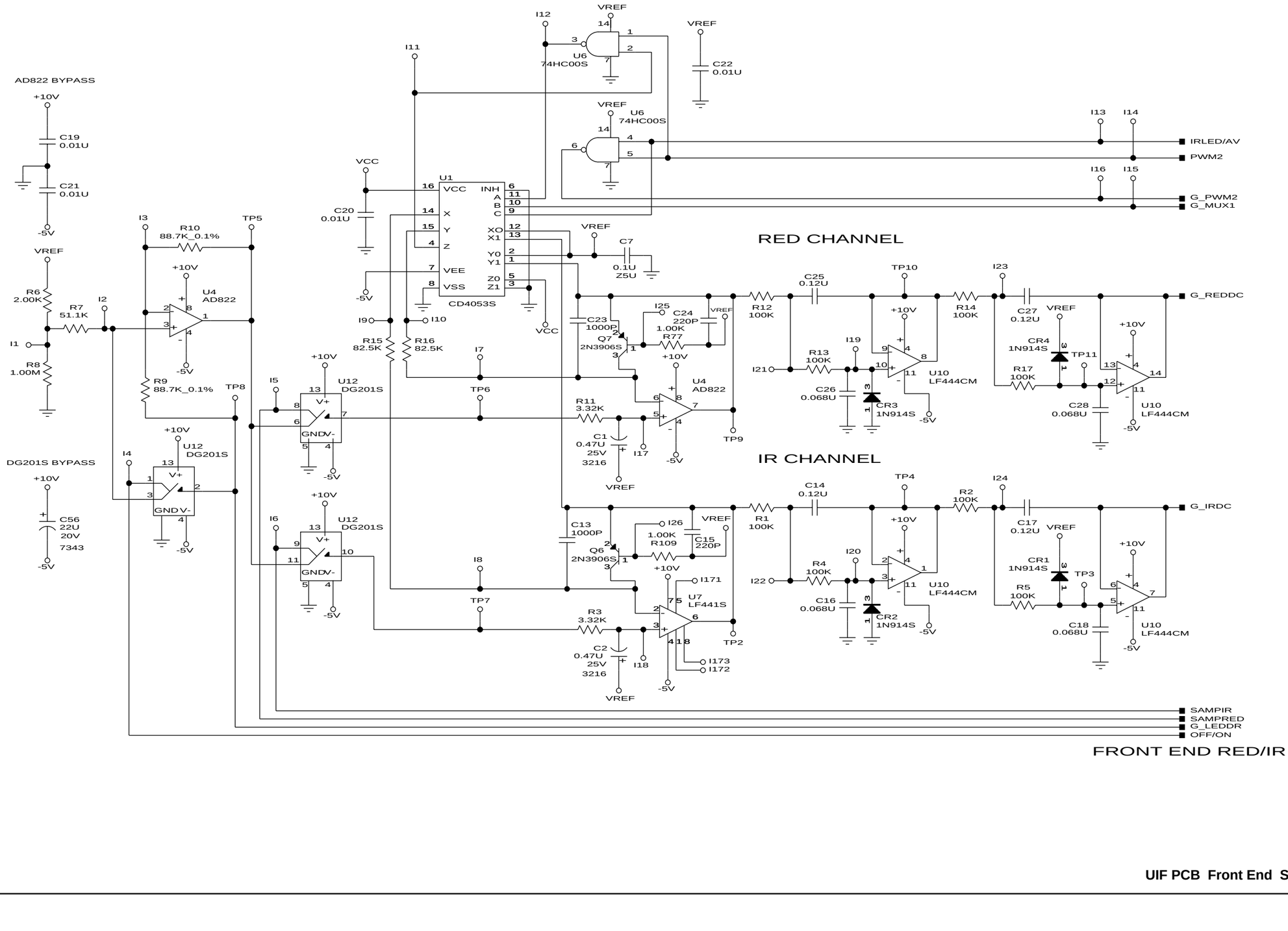


Figure 11-3
UIF PCB Front End Schematic Diagram

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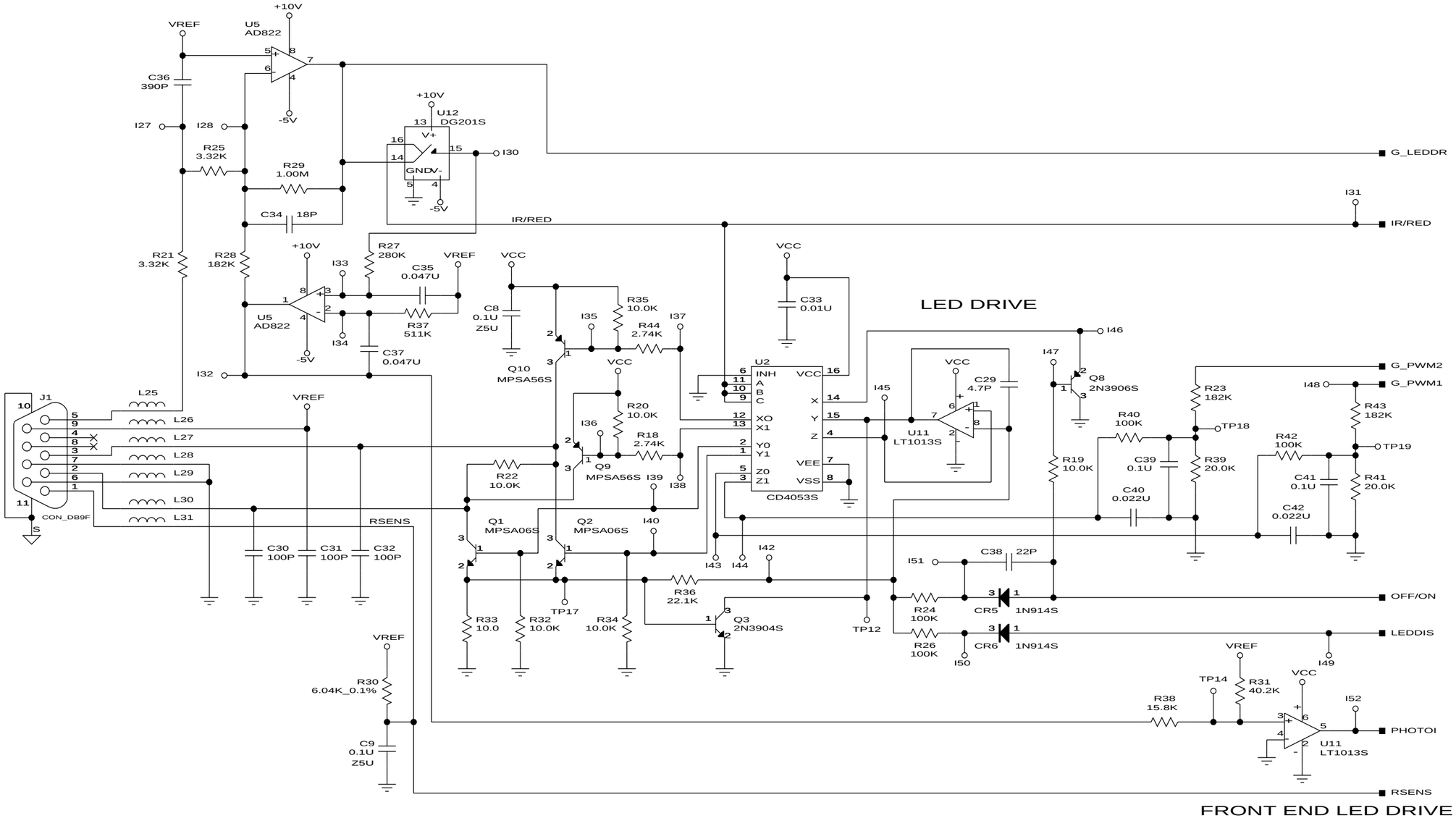
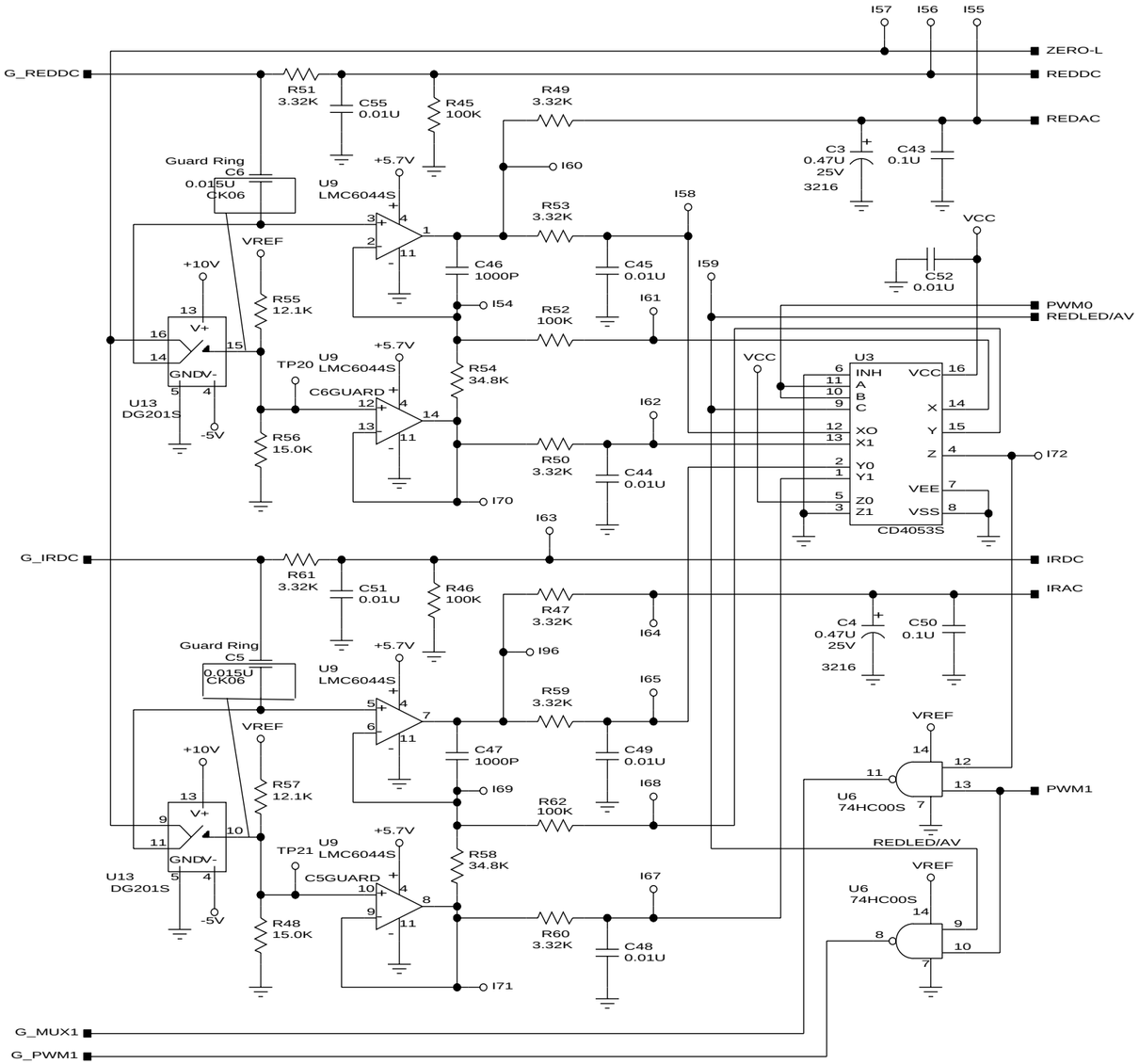
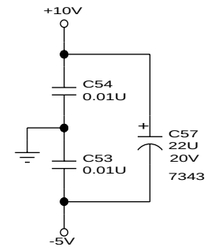


Figure 11-4
Front End LED Drive Schematic Diagram



DG201S BYPASS



DG201S SPARES

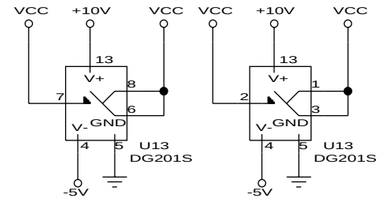


Figure 11-5
Front End Output Schematic Diagram

035262

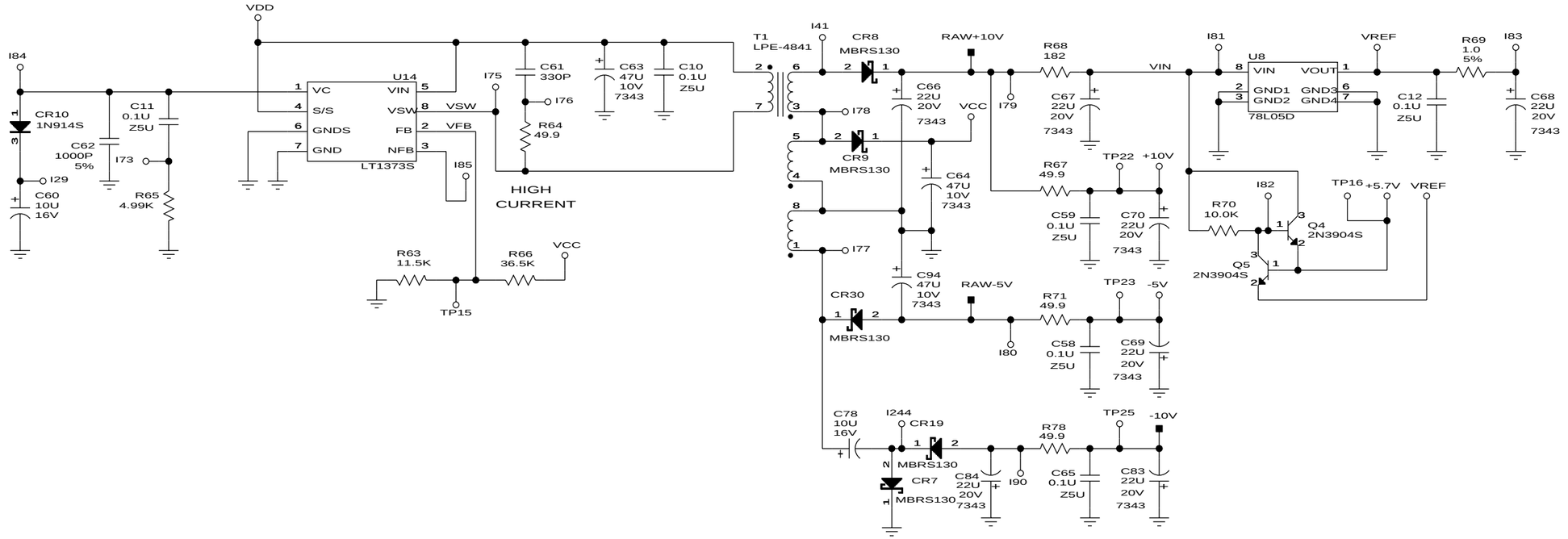


Figure 11-6
Front End Power Supply Schematic Diagram

035262

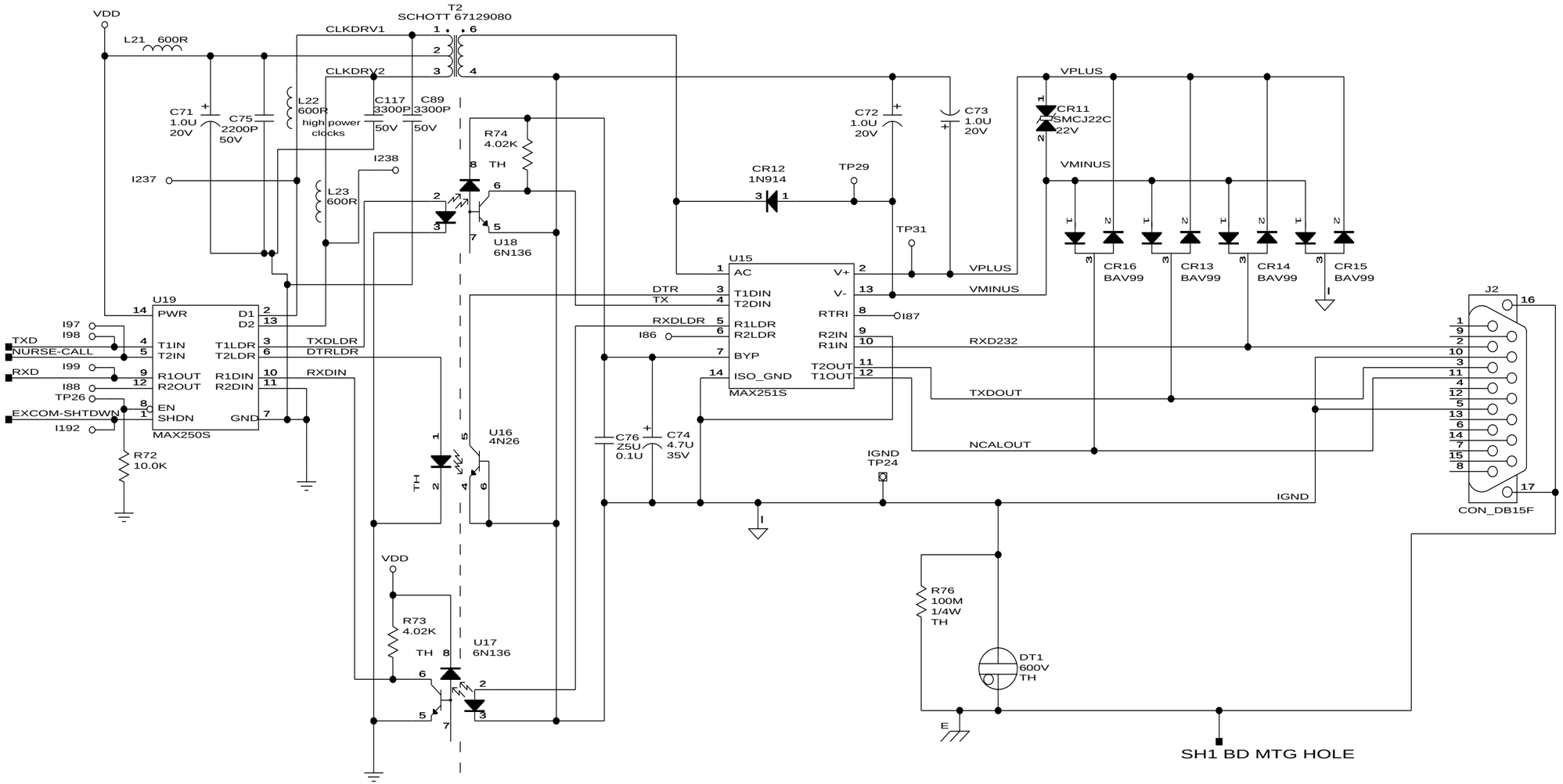


Figure 11-7
Isolation Barrier EIA-232 Port Schematic Diagram

035262

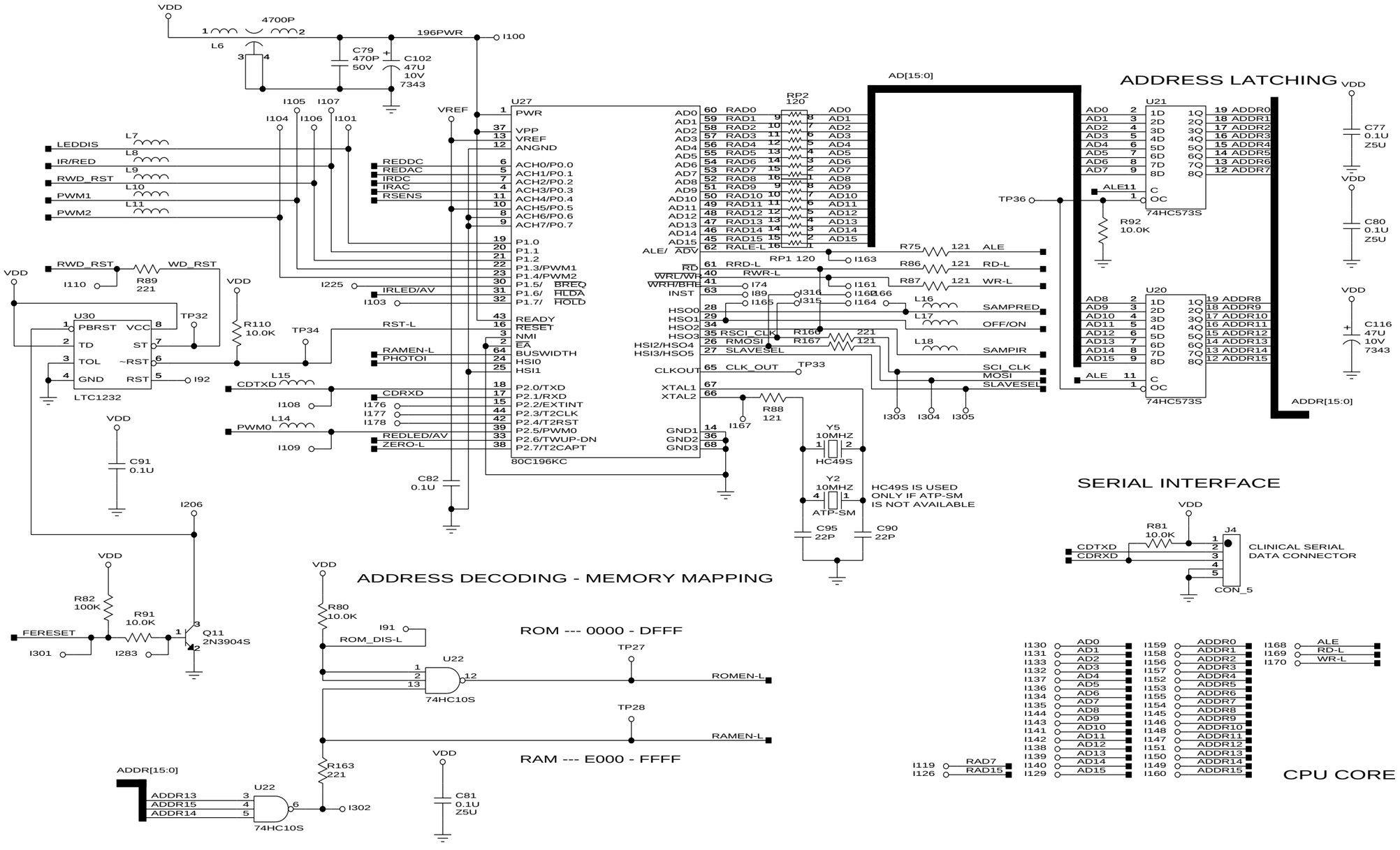


Figure 11-8
CPU Core Schematic Diagram A

035262

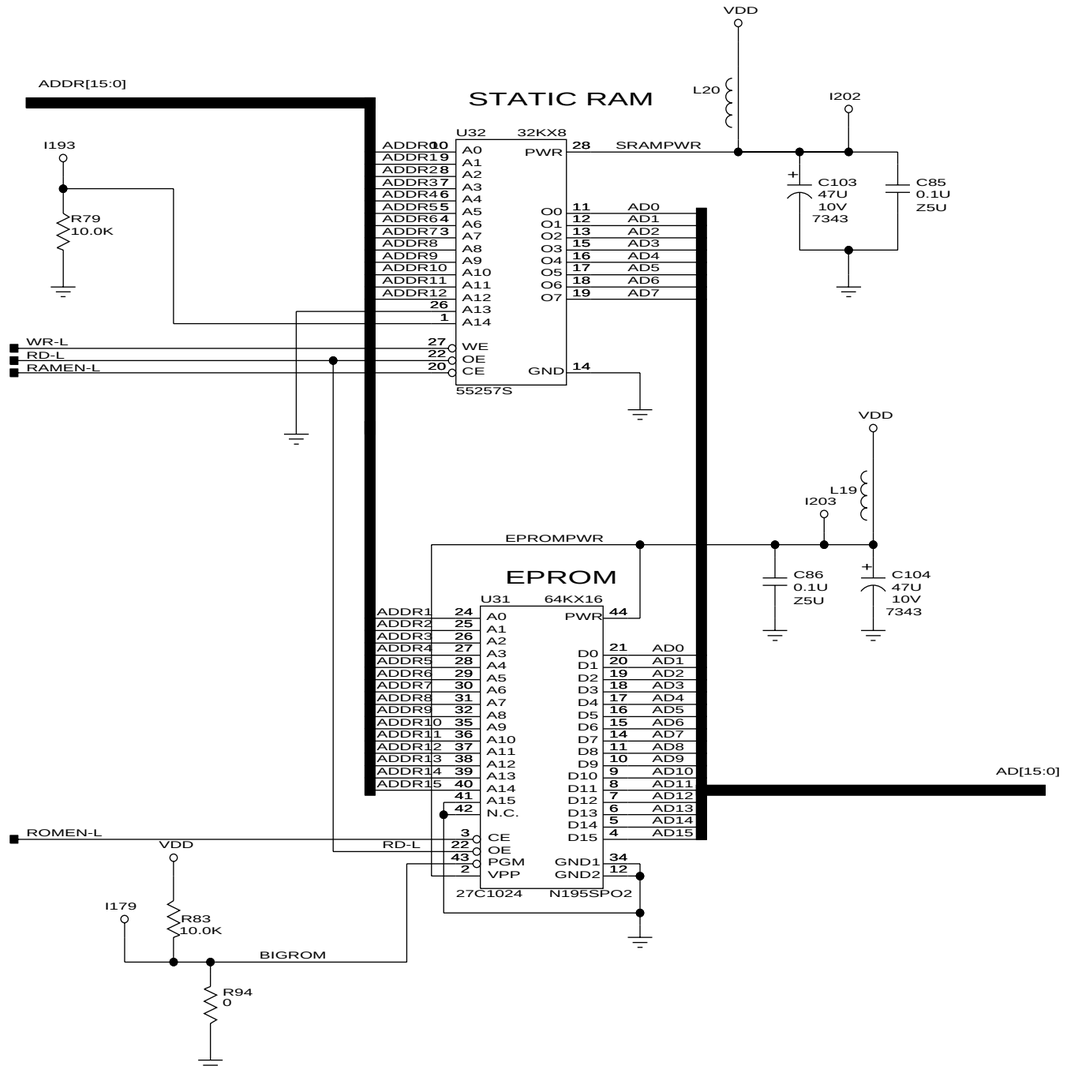


Figure 11-9
PIC and Speaker Schematic Diagram B

035262

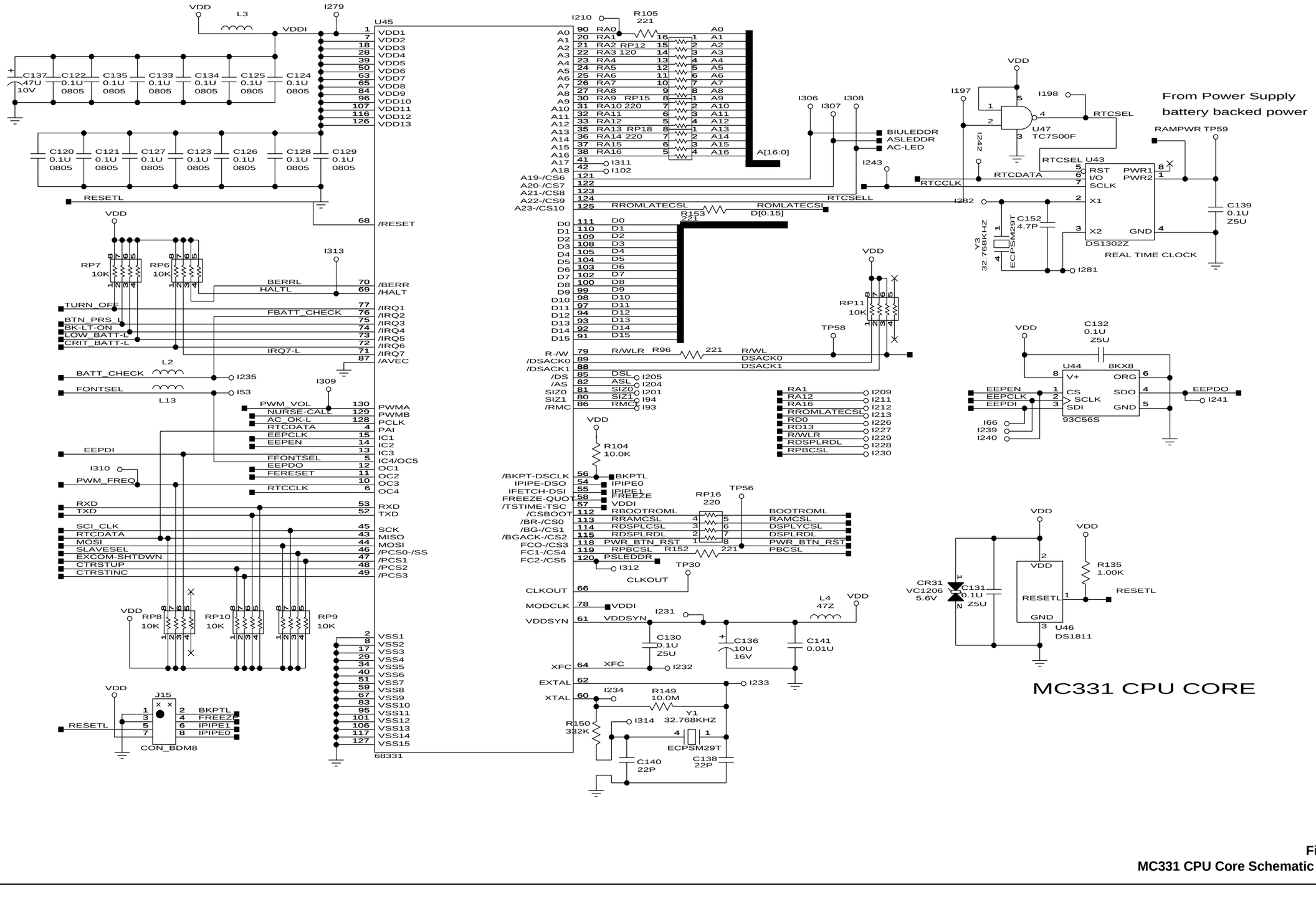


Figure 11-10
MC331 CPU Core Schematic Diagram A

035262

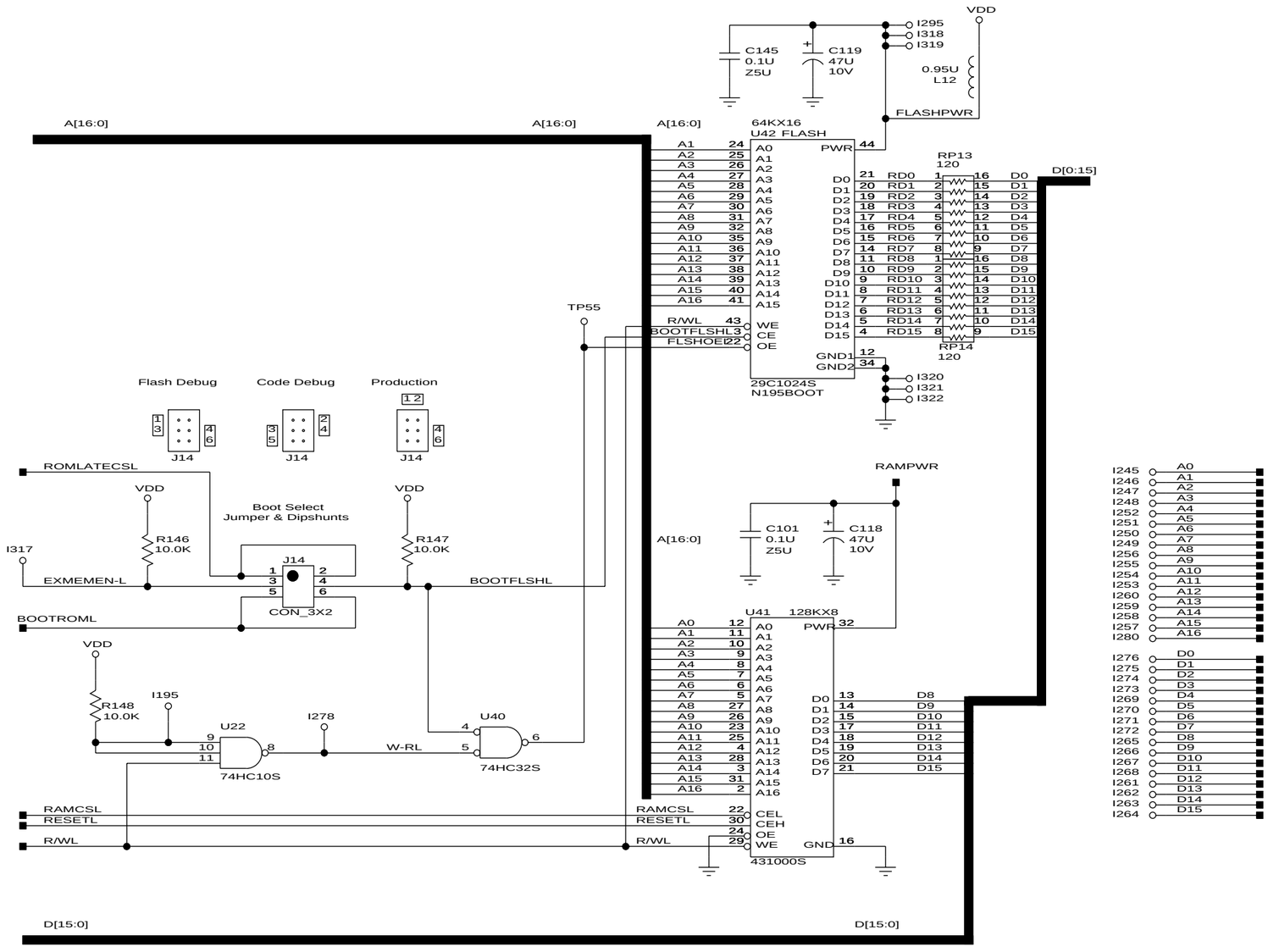


Figure 11-11
MC331 CPU Core Schematic Diagram B

035262

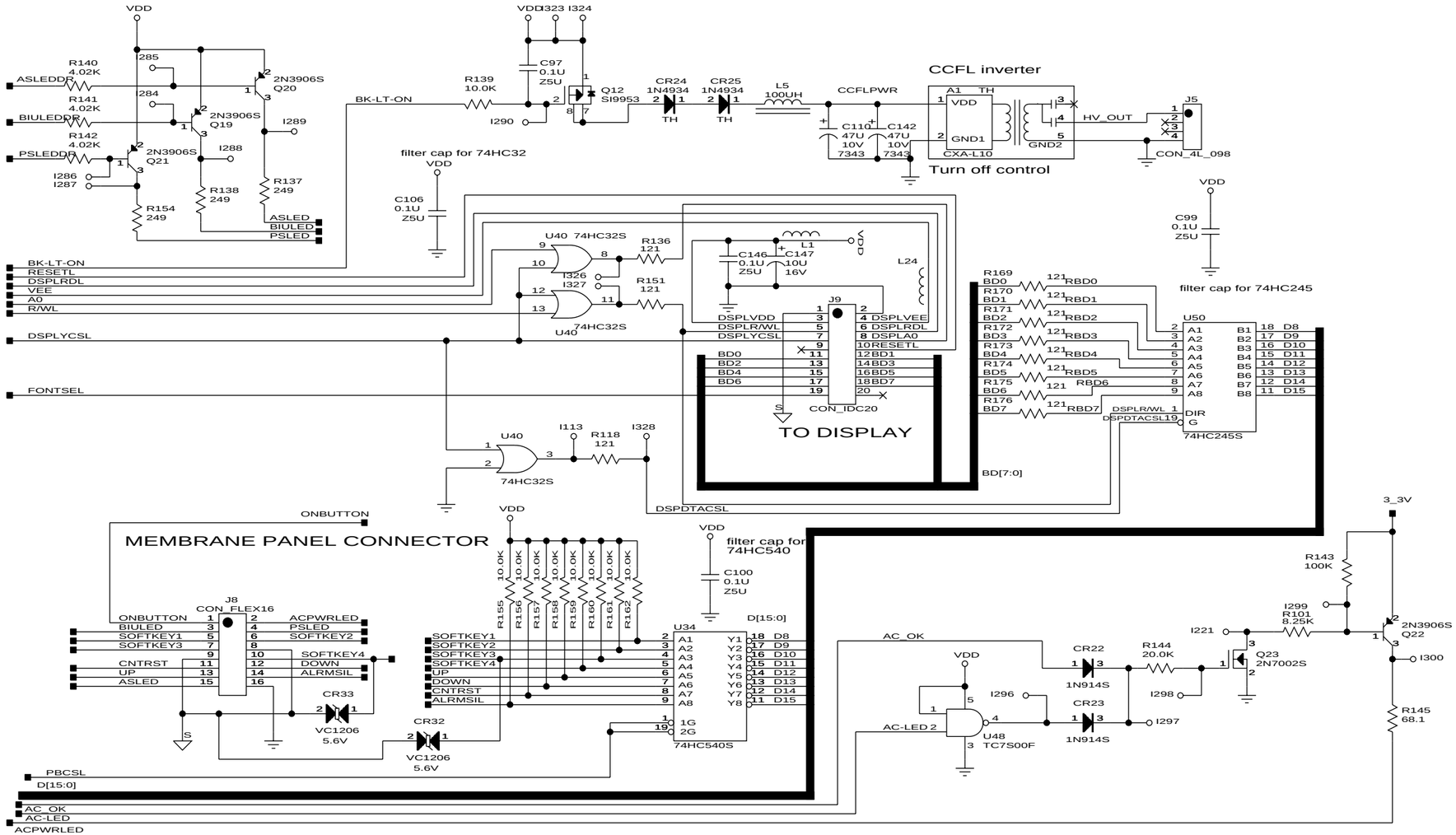


Figure 11-12
Display Driver Schematic Diagram

035262

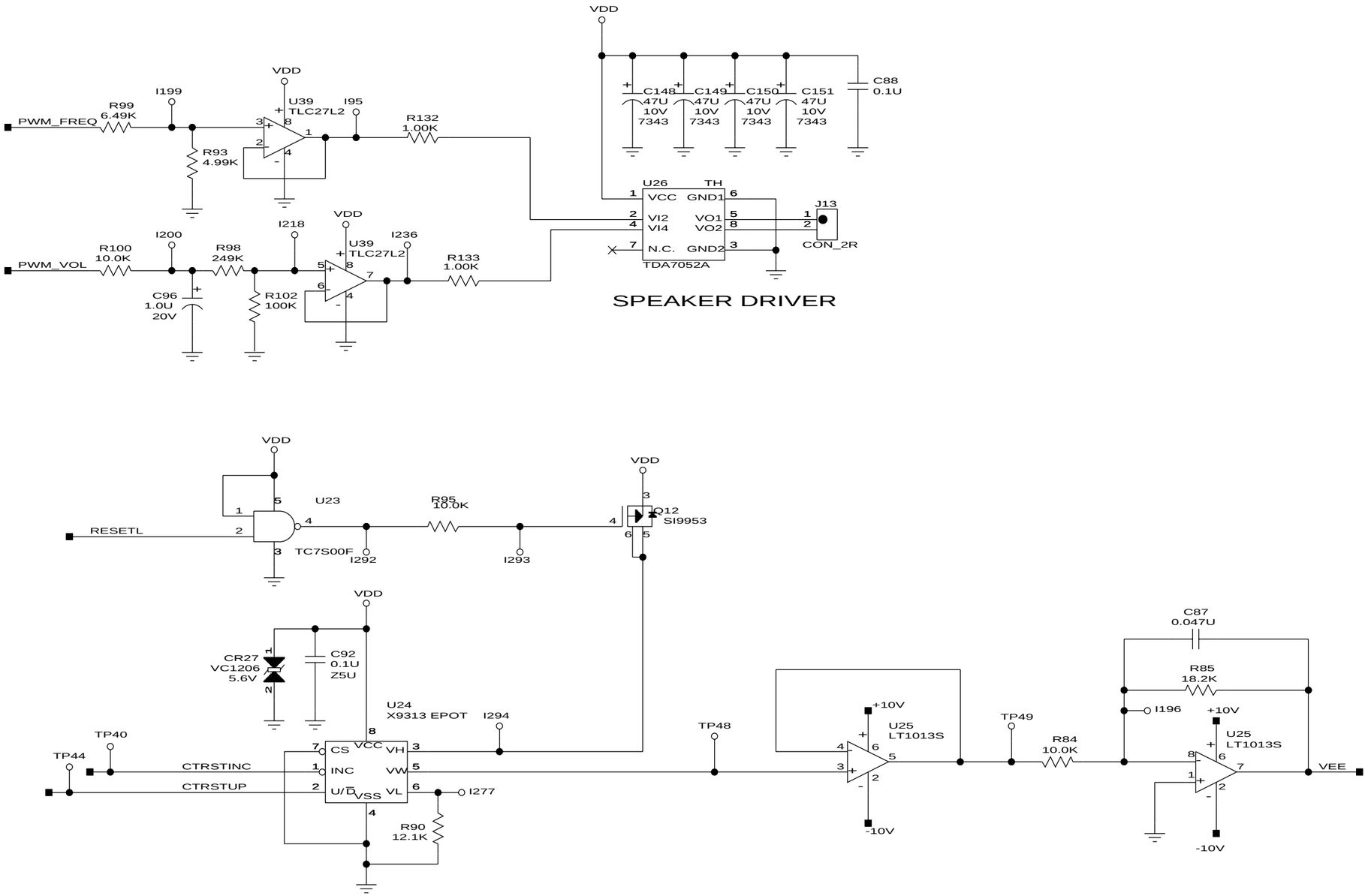


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Figure 11-13
Speaker Driver Schematic Diagram

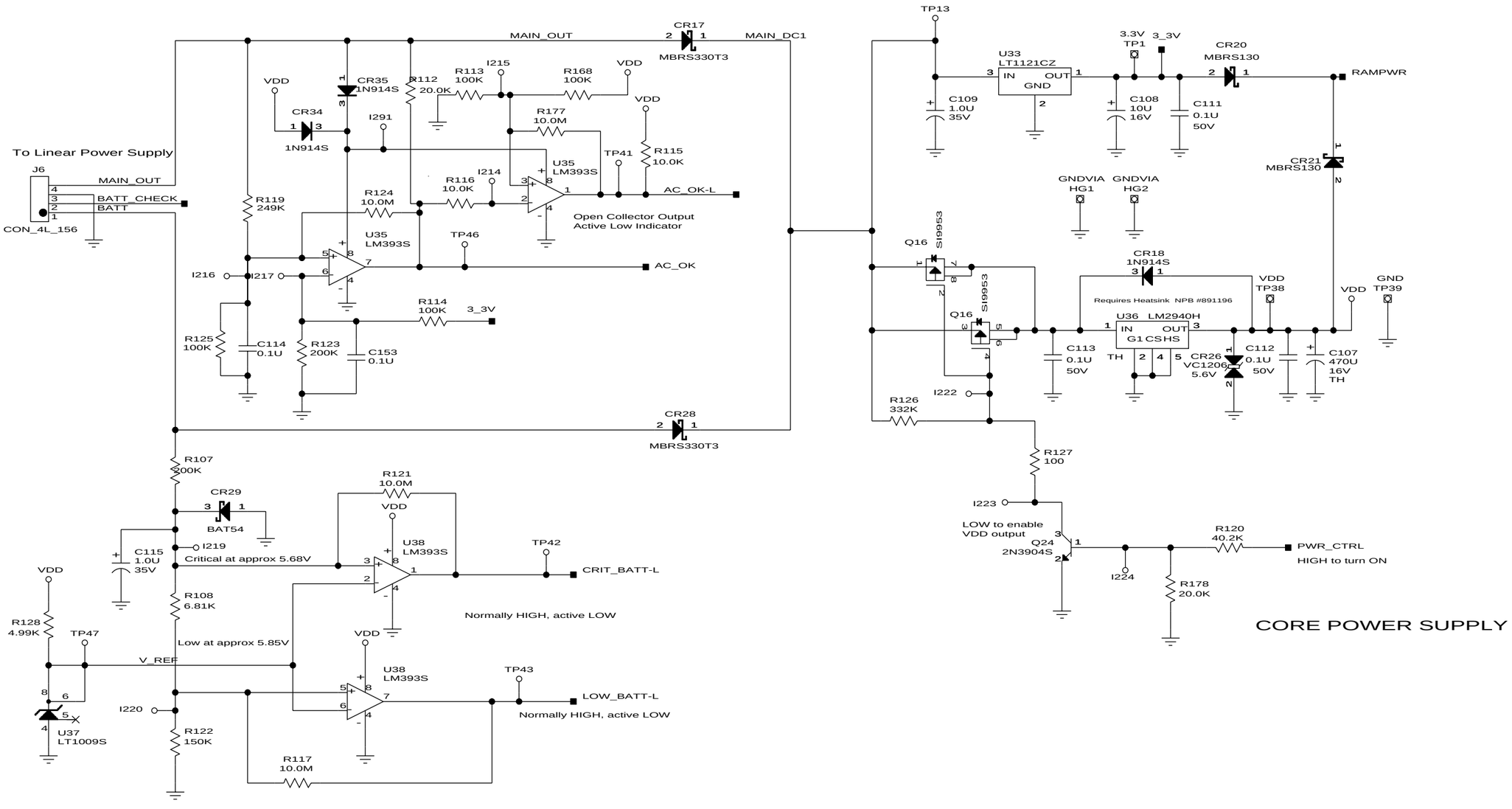

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Figure 11-14
Core Power Supply Schematic Diagram

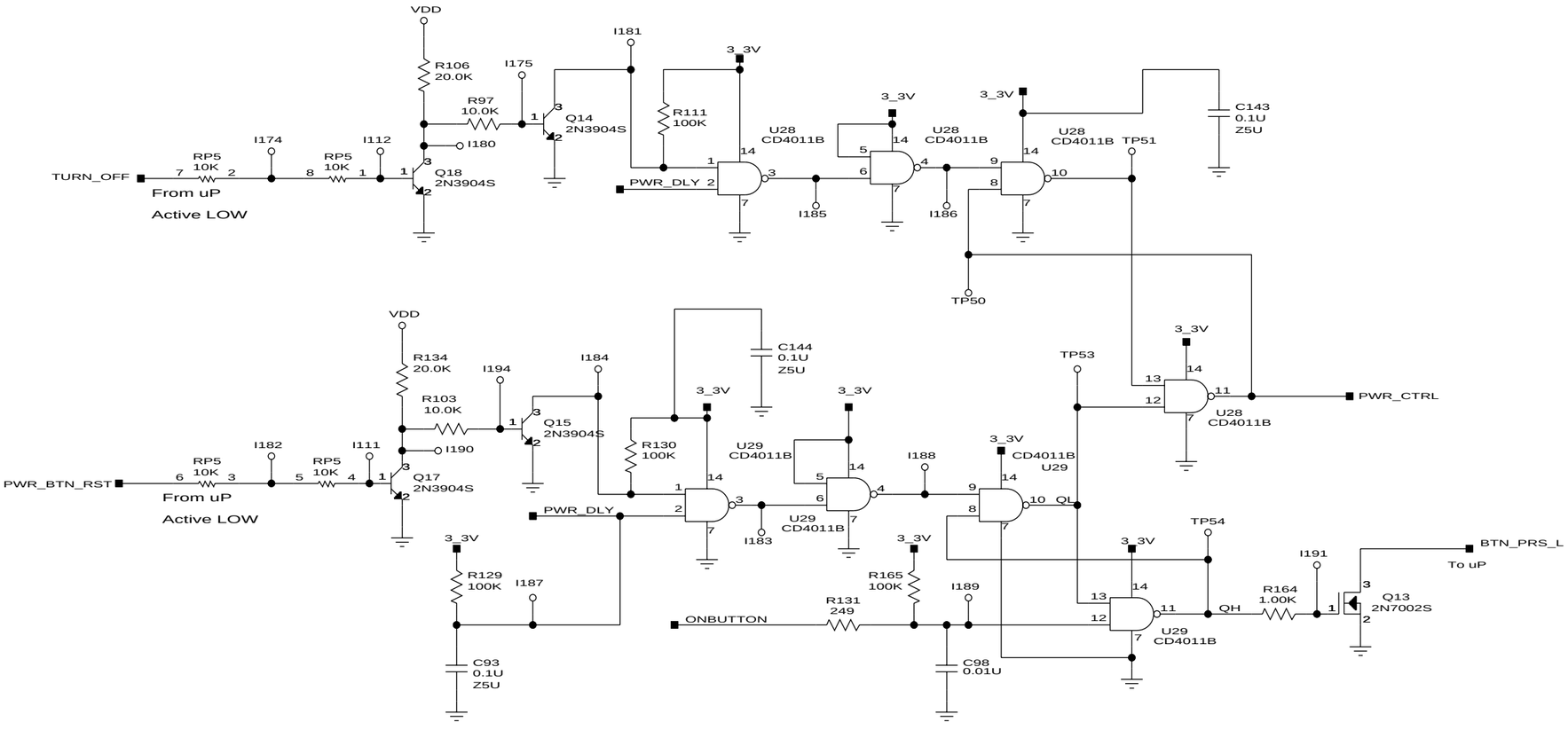
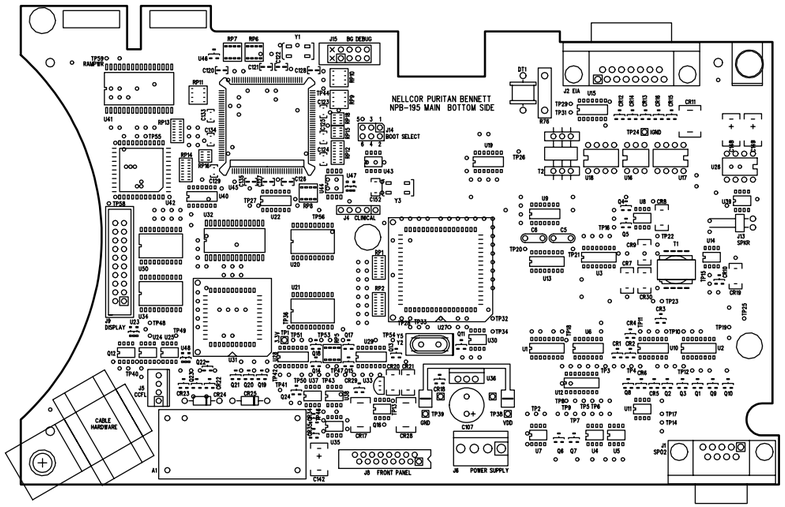
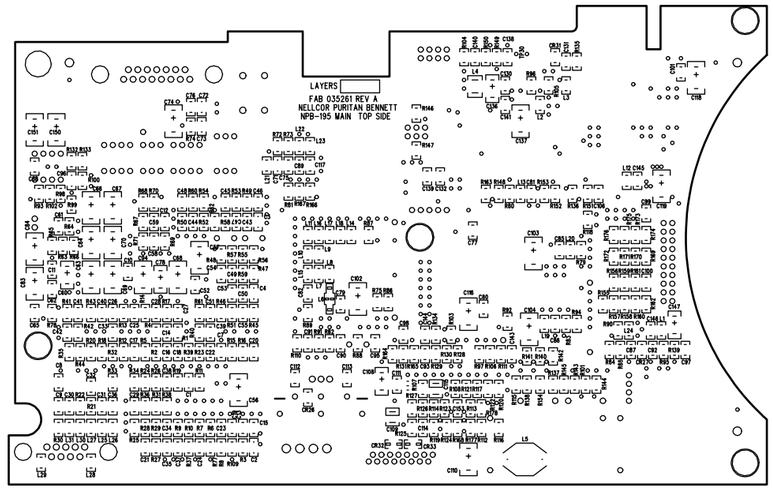


Figure 11-15
Power On/Off Circuit Schematic Diagram

035262



TOP SIDE



BOTTOM SIDE

035263

Figure 11-16
UIF PCB Parts Locator Diagram

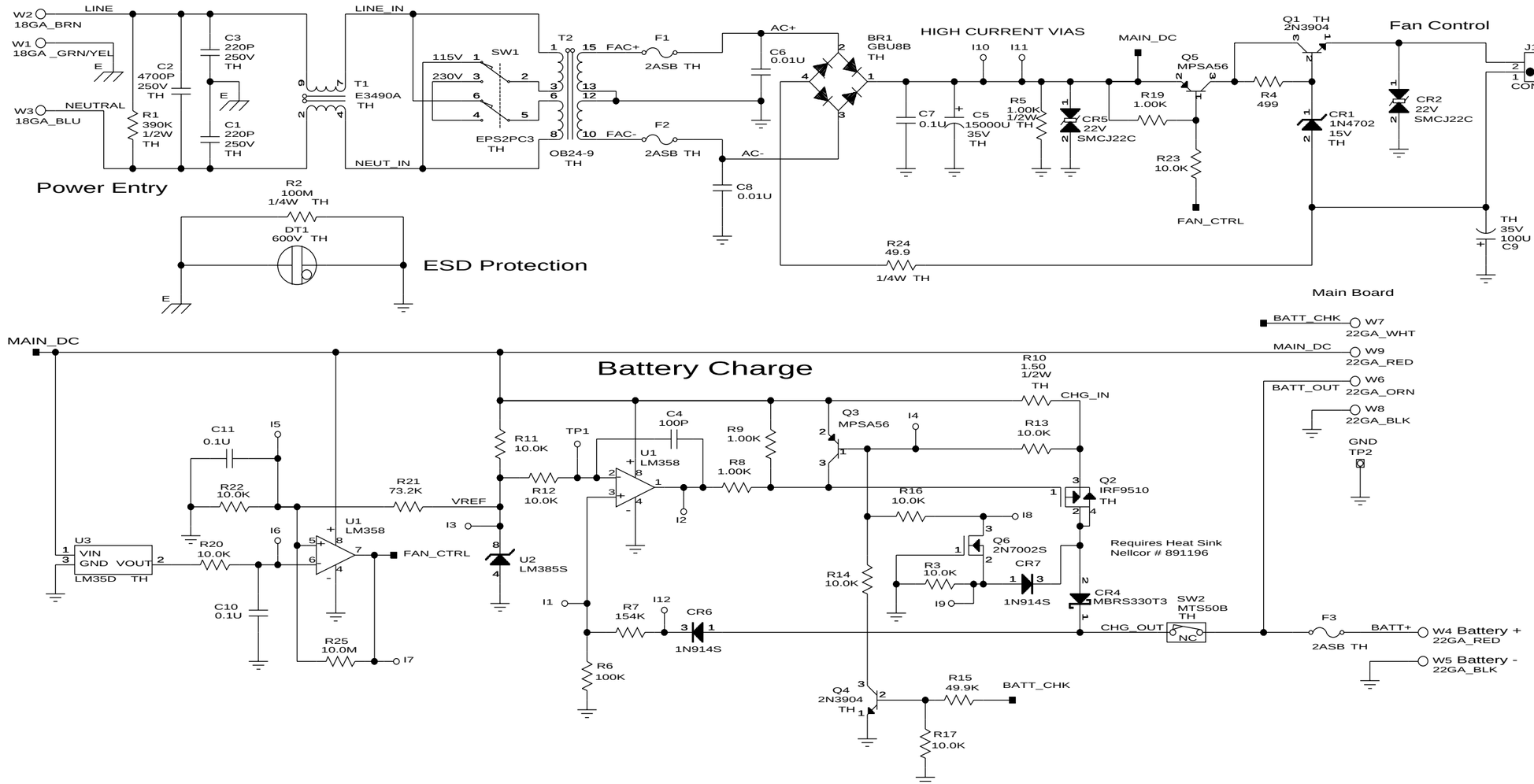


Figure 11-17
Power Supply Schematic Diagram

035199

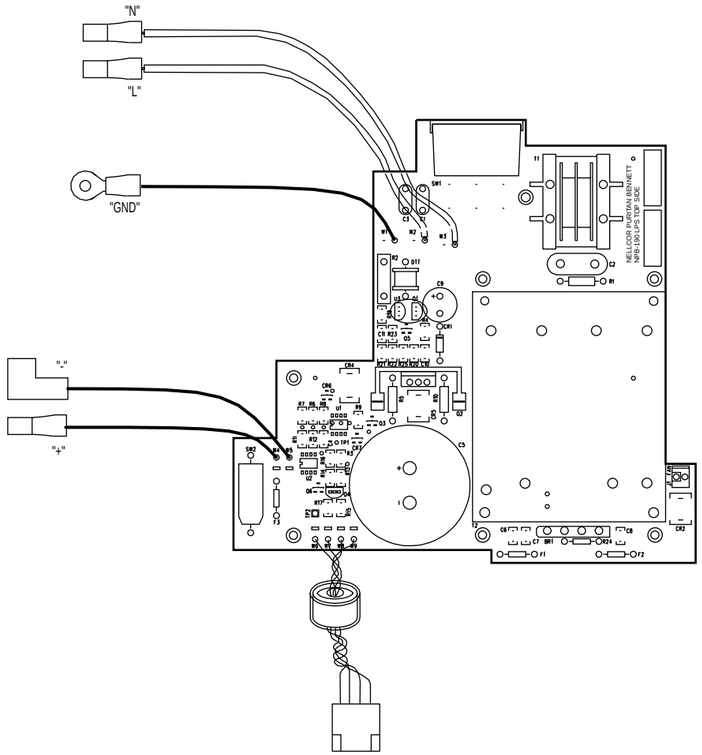


Figure 11-18
Power Supply Parts Locator Diagram

035200

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